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No. 10-_____

IN THE

Supreme Court of the United States

SCHERING CORPORATION,

Petitioner

v.

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, AND SHAWN JONES, ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

In this case, the Second Circuit concluded that Schering's pharmaceutical sales representatives fell outside of the FLSA's exemption for "outside salesm[e]n," 29 U.S.C. § 213(a)(1). The court found that the exemption does not apply because pharmaceutical sales representatives are barred by law from making a direct exchange of prescription drugs in return for consideration. The court reached its conclusion by giving controlling deference to the Secretary of Labor's arguments made in an *amicus* brief filed in *In re Novartis Wage & Hour Litigation*, 611 F.3d 141 (2d Cir. 2010), and adopting that analysis in this case. The questions presented are:

1. Whether *Auer* deference should be extended to an agency's interpretation of long-standing regulations when the interpretation causes unfair surprise, imposes extraordinary and unwarranted liabilities against an entire industry, and comes without the opportunity for notice and comment.

2. Whether the Second Circuit committed error in imposing new technical requirements on the outside sales exemption which subvert the purpose and goals of the FLSA and its implementing regulations.

PARTIES TO THE PROCEEDING

All parties are listed in the caption.

RULE 29.6 STATEMENT

Petitioner Schering Corporation is 100% owned by Merck & Co., Inc., a publicly traded company.

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PETITION FOR A WRIT OF CERTIORARI

Schering Corporation ("Schering") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals is available at 2010 WL 2669304 and is reprinted in Appendix ("App.") A. The opinion of the District Court for the District of Connecticut denying petitioner's motion for summary judgment is reported at 604 F. Supp. 2d. 385 and is reprinted in App. B.

JURISDICTION

The judgment of the court of appeals affirming the district court was entered on July 6, 2010. The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The statutes and regulations involved are the Fair Labor Standards Act, 29 U.S.C. § 201 *et seq.*, relevant regulations of the Department of Labor ("DOL"), 29 C.F.R. §§ 541.500-541.503, and portions of the Preamble to the final DOL regulations promulgated in 2004. Relevant excerpts from pertinent statutes and regulatory provisions are reproduced in the Appendix, App. D-L.

STATEMENT

The issue in this lawsuit, whether pharmaceutical sales representatives fall within the

FLSA's exemption for outside salespersons, is one of broad practical importance, not only for the pharmaceutical industry but for any business that employs a sales force. By virtue of its appearance in litigation pending before the Second Circuit, the Department of Labor has changed the regulation defining "sales" — and thus changed the definition of the exemption itself — in a manner that imposes substantial and unexpected liabilities on those businesses. The Second Circuit afforded DOL's interpretation "controlling deference" under *Auer v. Robbins*, 519 U.S. 452 (1997), and held that pharmaceutical sales representatives are not exempt outside salespersons.

The question of whether and when controlling deference should be granted to an agency's litigation stance, which has the potential to upend an entire industry with no notice and at enormous cost, is one of fundamental importance that can only be clarified and defined by this Court. The changes to the regulations arising from the deference afforded to DOL's interpretation do nothing to serve the stated goals underlying the FLSA; to the contrary, both the court's ruling and the Secretary's argument undermine the terms and the spirit of the Act while grossly penalizing an industry that employs thousands of sales employees across the country. These factors strongly support the grant of a writ of certiorari.

I. STATUTORY BACKGROUND

Congress enacted the FLSA to serve four goals: (1) to provide workers a minimum living wage; (2) to eliminate exploitative child labor; (3) to minimize the effects of an overworked labor force through

economic disincentives for overtime hours; and (4) to increase employment rates by making it more attractive to hire additional employees rather than to require existing employees to work overtime. *See generally* 29 U.S.C. § 202(a) (App. D at 79a). The Department of Labor has primary responsibility to administer and enforce the Act.

A. Congress carved out certain white-collar positions as exempt from the FLSA's overtime protections

The FLSA imposes various wage and hour requirements on employers, including, in Section 7(a)(1), the requirement that workers receive time-and-a-half overtime pay for work in excess of 40 hours in a workweek. 29 U.S.C. § 207(a)(1) (App. F at 81a). Exempt from these overtime requirements are a number of defined "white-collar" employees. *See id.* § 213(a)(1) (App. G at 83a).

The white-collar exemptions were premised on Congress's belief that employees in those occupations did not need the same level of protection provided to non-exempt employees. White-collar employees typically earned well in excess of the minimum wage and received "other compensatory privileges such as above average fringe benefits and better opportunities for advancement." Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22122, 22124 (Apr. 23, 2004) (App. L at 89a, 93a). Congress also recognized that the work performed by those employees "was difficult to standardize to any time frame." Their work "could not be easily spread to other workers after 40 hours in a week," thereby

"making compliance with the overtime provisions difficult" and "generally precluding the potential job expansion intended by the FLSA's time-and-a-half overtime premium." *Id.*

B. DOL made revisions to the white-collar regulations only after extensive notice-and-comment rulemaking

Since the FLSA's enactment in 1938, any employee employed "in the capacity of outside salesman" has been exempt from the Act's overtime pay requirements. 29 U.S.C. § 213(a)(1) (App. G at 83a). In light of the wide variations in industry practices, Congress did not itself define "outside salesman" but instead entrusted the Secretary of Labor to define and delimit the term through notice-and-comment rulemaking. *Id.* With regard to the white-collar exemptions generally, and the outside sales exemption specifically, the Secretary exercised the responsibility to undertake such rulemaking as recently as 2003. Suggested changes to the regulations had "been the subject of extensive public commentary for two decades." 69 Fed. Reg. at 22124 (App. L at 96a) (citations deleted).

On March 31, 2003, DOL published its Notice of Proposed Rulemaking (68 FR 15560) seeking comments to its proposed revisions to the white-collar exemptions. During the following 90-day comment period, DOL received over 75,000 comments from the public. 69 Fed. Reg. at 22125 (App. L at 92a). After considering those comments and making numerous changes to the regulations, DOL issued its final rule on August 23, 2004.

C. Recognizing that a sale may take place in a variety of ways in the modern workplace, DOL affirmed that an employee is exempt if the employee "in some sense" makes a sale

As explained in the preamble to its final rule, the Department recognized that it had to update its regulations to accommodate the modern workplace. It agreed "that technological changes in how orders are taken and processed should not preclude the [outside sales] exemption for employees who *in some sense* make the sales" and it re-emphasized that "obtaining a commitment to buy" was sufficient to satisfy the exemption. 69 Fed. Reg. at 22162-63 (App. I. at 105a) (emphasis supplied).

After taking into consideration the comments made by the public to the proposed rule, DOL defined the outside sales exemption, as it had in the past, by adopting the statutory language provided by Congress in defining the term "sale":

> The term "employee employed in the capacity of outside salesman" in section 13(a)(1) of the [FLSA] shall mean any employee:
>
> (1) Whose primary duty is:
>
> (i) making sales within the meaning of section 3(k) of the [FLSA], or
>
> (ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer; and

> (2) Who is customarily and regularly engaged away from the employer's place or places of business in performing such primary duty.

29 C.F.R. § 541.500(a) (App. H at 84a). Section 3(k) of the FLSA in turn defined "sale" to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k) (App. E at 80a).

The most significant change made to the exemption was the elimination of the limitation on the number of hours in which outside sales employees could be engaged in duties not related to sales. Despite concerns expressed by some commenters that employers would take advantage of the change, the restriction was lifted, largely because DOL determined that the outside sales position should be subject to the same primary duty standard applied to other white collar jobs. In support of its decision to apply the primary duty test to the outside sales exemption, the Department cited *Ackerman v. Coca-Cola Enterprises, Inc.*, 179 F.3d 1260, 1267 (10th Cir. 1999), for the proposition that the "determination of an employee's chief duty or primary function must be made in terms of the basic character of the job as a whole." 69 Fed. Reg. at 22161 (App. L at 103a).

II. FACTUAL BACKGROUND

Schering sells branded pharmaceutical products to treat a variety of diseases and disorders, including allergy and respiratory conditions, infectious diseases, cardiovascular disease, high cholesterol, and hepatitis. Schering develops these pharmaceuticals through its research and development efforts, but its corporate success

depends on its ability to sell prescription drugs. To achieve this end, it employs a network of pharmaceutical sales representatives to visit physicians, educate them about the benefits and risks of Schering's products versus those of the competition, and secure their commitment to prescribe Schering's products for their patients when indicated.

A. Federal law governs the manner in which pharmaceutical drugs may be sold

Like other pharmaceutical companies, Schering must conduct its business consistent with the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301 *et seq.*, and the accompanying regulations, 21 C.F.R. Parts 200-299 (the "FDCA"). One requirement imposed by those laws is that certain pharmaceutical products be dispensed by pharmacists pursuant to the "written prescription of a practitioner licensed by law to administer such drug[s]." 21 U.S.C. § 353(b)(1). Thus, under federal law, Schering cannot sell its prescription pharmaceuticals directly to the patients who ultimately consume them.

As a consequence of this legal regime, sales efforts in the pharmaceutical industry are necessarily directed at obtaining commitments from physicians to prescribe the company's products. These commitments cannot be legally binding, however, because physicians are ethically obligated to prescribe a drug only when it is clinically appropriate for the particular patient. *See, e.g., In re Novartis Wage & Hour Litig.*, 593 F. Supp. 2d 637, 650 (S.D.N.Y. 2009).

B. Respondents were experienced salespersons hired to perform sales duties for Schering

Respondents are former employees who worked for Schering during different periods between December 1980 and December 2006. They joined Schering after responding to postings for jobs that they understood to be sales positions requiring prior sales experience, which each Respondent had. They held various titles during their employment terms, all of which identified Respondents as sales representatives, and they were classified by Schering as exempt employees for purposes of the FLSA.

Respondents understood when they were hired, and throughout their employment, that they were expected to (i) create, achieve, and maximize sales objectives; (ii) create daily sales call schedules; (iii) implement plans to achieve sales objectives; (iv) have superior knowledge of the products they were selling; (v) meet with their customers; (vi) listen and respond to their customers' needs; (vii) persist with their customers if they would not commit; and (viii) maintain a positive relationship with their customers.

Schering provided Respondents extensive training on products and disease states as well as sales techniques. They became certified to sell particular drugs after an initial round of training and later participated in advanced training on those drugs. They were required to have complete knowledge of their products in order to sell those products convincingly to their customers — physicians and other healthcare providers.

Although Schering provided a list of targeted physicians in each territory, Respondents themselves determined which physicians to contact and when to do so, and they could call on physicians who were not on the list as well. Respondents analyzed sales data and tailored their sales calls to each physician. Their presentations routinely ended with the Respondent seeking a commitment from the physician to prescribe a particular product when a patient next presented with applicable indications.

C. Respondents obtained commitments from their customers to prescribe Schering's products

By virtue of the nature of the practice of medicine, a physician's commitment does not immediately result in an exchange of goods for cash. Instead, after learning about Schering products, physicians commit to prescribe the products to patients for whom they are appropriate. Respondents tracked their sales by physician to monitor their success and made repeated visits to them to develop an ongoing relationship. Respondents were skilled at building a rapport with the physicians, to whom they referred as their "customers."

D. Schering evaluated and paid Respondents based in large part on their selling skills and ability to grow sales within their assigned territories

Respondents worked independently, with only minimal supervision from their sales managers. They were evaluated based on their ability to satisfy sales objectives. On periodic visits, Respondents'

District Managers completed field coaching reports in which Respondents were rated on their "selling skills," such as proficiency at opening, questioning and probing, and confirming a medical provider's commitment. These field coaching reports tracked the market shares that pharmaceutical sales representatives were able to secure in their geographical areas.

Respondents received incentive pay after they met their sales targets, as measured by the number of Schering products prescribed within their geographical areas. And, their eligibility for merit-based pay increases depended on three criteria: sales results and market share, selling skills, and professional development. Respondents were well-compensated during their employment with Schering and routinely earned close to or more than $100,000 per year, including base salary and incentive compensation awarded as a result of sales success.

III. PROCEEDINGS BELOW

On February 13, 2007, Respondents filed their complaint alleging that they were entitled to overtime wages under the FLSA and seeking to represent themselves and other current and former pharmaceutical sales representatives in an opt-in collective action.

Schering moved for summary judgment on the ground that Respondents were exempt from FLSA overtime requirements under the "outside salesman" exemption. The district court denied the motion, holding that Respondents did not fall within the exemption because they did not make "sales" or obtain binding commitments from physicians. *Schering*, 604 F. Supp. 2d at 393-403 (App. B at 22a-

43a). The court relied heavily on the interpretive canon that exemptions from the FLSA's overtime requirements should be narrowly construed. *Id.* at 393, 395, 397, 398 n.14 (App. B. at 22a, 27a, 31a, 33a n.14).[1]

Notwithstanding its view of the law, the court acknowledged that "several district courts have weighed in differently on what is essentially the identical question." *Kuzinski v. Schering Corp.*, 614 F. Supp. 2d 247, 250 (D. Conn. 2009). The court therefore certified its decision for interlocutory appeal. *Id.* at 249-52.

Schering petitioned the Second Circuit to hear the appeal under 28 U.S.C. § 1292(b). The court granted the petition and directed that the case be heard in tandem with *In re Novartis Wage & Hour Litigation*, No. 09-0437 (2d Cir. 2009), an appeal from a decision of a district court in the Southern District of New York that reached the opposite conclusion on the same issue.

The Secretary of Labor appeared *sua sponte* in the *Novartis* appeal and took the position, for the first time ever, that pharmaceutical sales representatives are not exempt outside salespersons under the FLSA. Brief for the Secretary of Labor as *Amicus Curiae* in Support of Plaintiffs-Appellants, *In re Novartis Wage & Hour Litig.*, No. 09-0437 (2d Cir. Oct. 13, 2009) ("DOL Brief") (App. M at 110a). The Secretary argued that the "outside sales exemption" did not apply because pharmaceutical sales

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[1] Respondents do not dispute that they worked outside the employer's place of business as required by 29 C.F.R. § 541.502, App. J at 86a.

representatives do not consummate transactions or obtain any orders for prescription drugs. DOL Brief at 10 (App. M at 122a).

The Second Circuit afforded "controlling deference" to DOL's argument under this Court's decision in *Auer* and ruled that pharmaceutical sales representatives are not exempt outside salespersons. *In re Novartis Wage & Hour Litig.*, 611 F.3d 141 (2d Cir. 2010) (App. C at 45a). Adopting the reasoning stated in *Novartis*, the court affirmed the trial court's order in *Schering* by summary order. *Kuzinski v. Schering*, 2010 WL 2669304, at *1 (2d Cir. July 6, 2010) (App. A at 3a).

REASONS FOR GRANTING THE PETITION

The appropriateness of the Second Circuit's application of outcome-determinative deference to an interpretation which was a clear departure from the Department's past position is an important question of federal law warranting the granting of the petition. *Auer* requires courts to accord deference to an agency's interpretation of its own regulations in certain, but not all, cases. Without the imposition of appropriate boundaries for *Auer* deference, agencies may use *amicus* briefs to subvert the normal rulemaking processes and avoid formal notice-and-comment procedures which provide accountability and prevent *de facto* rulemaking, unfair surprise, and the attendant potential imposition of massive and unanticipated overtime liability. This Court's guidance is needed to clarify those boundaries.

Moreover, before the filing of DOL's *amicus* brief, it was clear that an employee who promotes a tangible good to customers may properly be classified as an exempt outside salesperson even if that

employee does not engage with the customer in a direct exchange of the good for consideration. It was enough if the customer placed the order himself by calling or ordering the product online after the sales pitch made by the employee.

With its appearance here, DOL ignored its prior acknowledgment that sales may be made in a variety of ways in the modern workplace. Instead, DOL argued — and the Second Circuit deferred to the argument — that employees who applied for sales jobs, were trained in selling skills, were charged with the duty to sell the company's products, were evaluated on their selling skills, were actively involved in developing business plans designed to grow sales in their assigned territories, and were compensated, in part, on their ability to grow sales were not, in fact, salespersons. The exemption did not apply, under DOL's view, merely because those employees are barred by law from delivering prescription drugs to physicians in return for consideration. The writing of the prescription was not enough. Yet, under the realities of the pharmaceutical industry, the only way to obtain a prescription drug is with a prescription. It is the writing of the prescription that makes the transaction equivalent to that of the customer who, after a sales pitch by a door-to-door salesperson, places his order online.

To reach its decision, the Second Circuit committed error by relying on DOL's new and heightened requirement that a direct transaction be consummated between sales representative and customer. It ignored the reality of how prescription drugs are sold and DOL's own guidance that the

"basic character of the job as a whole" should be considered when applying the outside sales exemption. 69 Fed. Reg. at 22161 (App. L at 103a). Because of the extraordinary impact on all sales industries made by the Second Circuit's decision to defer to DOL's litigation argument and the magnitude of the error in construing the outside sales exemption, Schering's petition should be granted.

I. THE COURT'S GUIDANCE IS NEEDED TO CLARIFY THE APPROPRIATE SCOPE OF *AUER* DEFERENCE

In *Auer*, the Court invited DOL's input to interpret regulations related to the salary-basis test under the FLSA. Because the salary-basis test "is a creature of the Secretary's own regulations," the Court concluded that DOL's interpretation should be granted controlling deference, unless the interpretation was "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461 (internal citations omitted). Important to the Court's decision was the conclusion that DOL's interpretation did not pose a threat of "massive and unanticipated overtime liability." *Id.*

Here, despite the threat of massive and unanticipated overtime liability being faced by Schering and the pharmaceutical industry overall with its ruling, the Second Circuit determined that DOL's litigation stance was entitled to controlling deference with little more than a passing reference to *Auer*. No discussion was had of the implications of the change in DOL stance nor did the court address the unfair surprise being faced by the

pharmaceutical industry and the extraordinary impact of the agency's change in position on all businesses employing an outside sales force. The Second Circuit's default to deference, without analysis, in circumstances such as these demonstrates that this Court's guidance is needed.

A. The Court's guidance is needed to clarify the extent to which *Auer* deference should be granted when a change in agency interpretation, without notice and comment, creates massive and unexpected liabilities

Auer deference should not be extended to a case where an agency, uninvited, interprets its regulations in a manner that subjects a company or industry to extraordinary liability without fair notice. The language and purpose of the FLSA's "outside sales" provision, and the Department of Labor's longstanding interpretation of it, all point in the same direction: that pharmaceutical sales representatives are exempt. It would be unjust to allow the Department's unanticipated argument that those sales positions are *not* exempt, announced for the first time in an *amicus* brief, to be the deciding factor in litigation involving virtually all major pharmaceutical companies and thousands of employees. *Cf. Christopher v. SmithKline Beecham Corp.*, No. CV-08-1498-PHX-FJM, 2010 WL 396300, at *2 (D. Ariz. Feb. 1, 2010) (consolidated appeal pending in the Ninth Circuit) (concluding that the DOL Brief was not entitled to deference; "[n]ot only is the DOL's current interpretation inconsistent with

the statutory language and its prior pronouncements, but it also defies common sense").

The Court recently analyzed the potential for disruption and unfair surprise caused by deference to informal agency opinions in *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158 (2007). At issue in *Coke* was DOL's interpretation of two conflicting regulations concerning the treatment under the FLSA of domestic companionship services providers employed by third parties. 551 U.S. at 169. There the Court noted that deference to agency interpretations was only appropriate "as long as interpretative changes create no unfair surprise." *Id.* at 170. In that case, the Court found no such threat because DOL announced its position in a notice-and-comment rulemaking procedure. *Id.* at 170-71. Accordingly, there was no need for the Court to articulate guidelines for applying the "unfair surprise" standard. That need for guidelines, however, exists here. The changes made by DOL — requiring that a salesperson obtain a "binding" commitment or consummate a transaction to be classified as exempt — were not subject to the requisite rulemaking procedures and have created unfair surprise. *Cf. Upton v. S.E.C.*, 75 F.3d 92, 98 (2d Cir. 1996) (explaining that deference should not be extended to an agency's interpretation if it "would penalize [a company that] has not received fair notice of a regulatory violation").

Two of the circuit courts have likewise grappled with the extension of *Auer* and the effect of unfair surprise post-*Coke*, albeit with divergent results. *See Taylor v. Progress Energy, Inc.*, 493 F.3d 454, 461-62 (4th Cir. 2007) (without discussing *Coke*, majority

does not give deference to position advanced in *amicus* brief because it is inconsistent with the statute and accompanying regulations at issue; dissent mentions *Coke* "unfair surprise" standard); *Boose v. Tri-County Metro. Trans. Dist. of Or.*, 587 F.3d 997, 1005 n. 13 (9th Cir. 2009) (finding no unfair surprise under *Coke* because agency attempted to change its position through notice-and-comment rulemaking); *Pub. Citizen v. Nuclear Regulatory Comm'n*, 573 F.3d 916, 923-24 (9th Cir. 2009) (where agency is merely "elaborating on" the interpretation of its own regulation, it is not departing from an "established standard" and there is no unfair surprise).

This Court's guidance on the extension of *Auer* to the DOL Brief, and clarification of *Coke*'s "unfair surprise" standard, is particularly important in a case such as this, one which threatens unfair surprise not only to an individual company and the pharmaceutical industry overall but also other sales organizations who relied on DOL's regulations allowing exempt status for those employees who "in some sense" made a sale.

Before DOL interceded in *Novartis*, employers only had to assure that their sales employees "direct[ed] efforts toward the consummation of a sale" or made a sale "in some sense," even if it was the customer who actually finalized the order. 29 C.F.R. § 541.503(c) (App. K at 87a); 69 Fed. Reg. at 22162 (App. L at 105a). Under DOL's new interpretation of the regulations, an employer must now ask whether its outside sales force actually "consummates" transactions or obtains legally binding commitments in order to classify those

employees as exempt. DOL's interpretation raises questions for all industries where there may be a long sales cycle, requiring salespersons to make multiple visits to customers before a final sale is consummated, or where someone other than the salesperson or customer pushes the button finalizing the order.

The need for guidance is further strengthened in light of DOL's election to engage in the argument only after the great majority of courts to consider the question had concluded, consistent with the Department's previously expressed views, that pharmaceutical sales representatives *are* exempt outside salespersons.[2] Granting this petition will

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[2] *See Christopher*, 2009 WL 4051075, at *5; *Schaefer-LaRose v. Eli Lilly & Co.*, 663 F. Supp. 2d 674, 688 (S.D. Ind. 2009); *Harris v. Auxilium Pharms., Inc.*, 664 F. Supp. 2d 711, 742 (S.D. Tex. 2009); *Baum v. AstraZeneca LP*, 605 F. Supp. 2d 669, 686 (W.D. Pa. 2009), *aff'd on other grounds*, 372 F. App'x 246 (3d Cir. 2010); *Delgado v. Ortho-McNeil, Inc.*, No. SACV 07-00263-CJC(MLGx), 2009 WL 2781525, at *5 (C.D. Cal. Feb. 6, 2009) (consolidated appeal pending in the Ninth Circuit); *Yacoubian v. Ortho-McNeil Pharm., Inc.*, No. SACV 07-00127-CJC(MLGx), 2009 WL 3326632, at *6 (C.D. Cal. Feb. 6, 2009) (same); *see also Rivera v. Schering Corp.*, No. CV 08-1743-GW(JCx), 2008 WL 6953955, at *9 (C.D. Cal. Aug. 14, 2008) (California law); *Brody v. AstraZenca Pharms. LP*, No. CV 06-6862-ABC(MANx), 2008 WL 6953957, at *9 (C.D. Cal. June 11, 2008) (same); *Menes v. Roche Labs., Inc.*, No. 07 CV 01444-ER-FFMx, 2008 WL 6600518, at *2 (C.D. Cal., Jan. 7, 2008) (same); *Barnick v. Wyeth*, 522 F. Supp. 2d 1257, 1265 (C.D. Cal. 2007) (same); *D'Este v. Bayer Corp.*, No. CV 07-3206-JFW(PLAx), 2007 WL 6913682, at *4 (C.D. Cal. Oct. 9, 2007) (same). *But see Jirak v. Abbott Labs., Inc.*, No. 07-C-3626, 2010 WL 2331098, at

allow the Court to prevent an entire industry and other businesses engaged in the making of sales from being penalized for a regulatory violation about which no notice had been given and no opportunity for comment had been allowed.

Extending *Auer* deference in this case, on the other hand, would allow a position articulated for the first time in an *amicus* brief to subvert the normal rulemaking processes. Under the "unfair surprise" analysis described in *Coke*, *Auer* deference is justified only when "an agency's course of action indicates that the interpretation of its own regulation reflects its considered views," as, for example, when the agency has "clearly struggled with the * * * question" for an extended period. *Coke*, 551 U.S. at 171. There is no indication that DOL has *ever* "struggled with" the question whether pharmaceutical sales representatives are outside salespersons. On the contrary, the Department's "course of action" since the FLSA's enactment demonstrates that its current position reflects an abrupt *change* in its views. Granting the petition in this case will allow the Court to define the limits on *Auer* deference and guide DOL and other agencies in the future application of such deference.

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*7 (N.D. Ill. June 10, 2010); *Smith v. Johnson & Johnson*, No. 06-4787 (JLL), 2008 WL 5427802, at *7 (D.N.J. Dec. 30, 2008), *aff'd on other grounds*, 593 F.3d 280 (3d Cir. 2010); *Ruggeri v. Boehringer Ingelheim Pharms., Inc.*, 585 F. Supp. 2d 254, 272 (D. Conn. 2008); *Amendola v. Bristol-Myers Squibb Co.*, 558 F. Supp. 2d 459, 472 (S.D.N.Y. 2008).

B. The Court's guidance is needed to clarify the limitations on *Auer* deference when the regulation mirrors the statutory language

In deciding to extend *Auer* deference to the Secretary's interpretation of whether pharmaceutical representatives make "sales," the Second Circuit considered, and rejected, the argument that deference was not due because the regulation being interpreted merely parrots the statute. *Novartis*, 611 F.3d at 151-52 (App. C at 64a-75a). It did so by looking to regulations not relevant to the question being litigated. The court disregarded *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006), and its instruction that *Auer* deference is not warranted where "the underlying regulation does little more than restate the terms of the statute." This Court's guidance is needed to clarify the extent to which *Gonzales* impacts *Auer* deference.

The question in this case is whether pharmaceutical sales representatives make "sales." To answer that question, DOL interpreted the regulations to conclude that the definition of "sales" requires a binding commitment or a consummated transaction. DOL Brief at 6-13 (App. M at 120a-124a). The regulation defining the word "sale," however, exactly mirrors the words crafted by Congress and nowhere states that commitments must be legally binding or transactions must be consummated.

Congress defined "[s]ale' or 'sell' under section 3(k) of the FLSA to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k) (App. E

at 80a). The regulations begin with section 541.500, which provides that an employee is exempt if his or her primary duty is "making sales within the meaning of section 3(k) of the Act." 29 C.F.R. § 541.500(a)(1)(i) (App. H at 84a). Going further, section 541.501 of the regulations notes that "Section 541.500 requires that the employee be engaged in * * * [m]aking sales within the meaning of section 3(k) of the Act." It then quotes the definition of sale originally set forth by Congress: "Section 3(k) of the Act states that 'sale' or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 C.F.R. § 541.501(b) (App. I at 85a).

Nonetheless, the Second Circuit disagreed that the regulations merely parroted the statute. To conclude that the Secretary's interpretations were entitled to controlling deference, the court instead looked to non-definitional regulations explaining that sales are not limited to tangible goods, (29 C.F.R. § 541.501(b) (App. I at 85a)), and addressing the extent to which an outside salesperson may engage in promotional activities (*id.* § 541.503) (App. K at 87a). *Novartis*, 611 F.3d at 152-53 (App. C at 68a-69a). Those regulations upon which the court relied, however, do not answer the question present here of whether an employee in fact makes sales. The court's reliance on those regulations to conclude that controlling deference was warranted demonstrates the need for the Court's guidance in clarifying the interplay between *Auer* and *Gonzales*.

II. THE SECOND CIRCUIT ERRED IN ITS CONSTRUCTION OF THE OUTSIDE SALES EXEMPTION

The position taken by the Second Circuit and DOL in this case is at odds not only with the spirit of the FLSA and the less restrictive approach taken by other courts but also with the position DOL has taken for nearly three quarters of a century. DOL has emphasized, in myriad ways, the breadth and flexibility of the concept of a "sale" under the "outside sales" exemption. As the Department said in 1940, and as it said again in 2004 after extensive notice-and-comment rulemaking, the exemption applies to an employee who "in some sense" makes sales. 69 Fed. Reg. at 22162 (App. L at 105a) (citing U.S. Dep't of Labor, Wage & Hour Div., *"Executive, Administrative, Professional . . . Outside Salesman" Redefined: Report and Recommendations of the Presiding Officer (Harold Stein) at Hearings Preliminary to Redefinition* 45 (Oct. 10, 1940)).

Relying upon DOL's new interpretation, however, the Second Circuit concluded that, because a pharmaceutical sales representative "cannot lawfully transfer ownership of any quantity of the drug in exchange for anything of value, cannot lawfully take an order for its purchase, and cannot lawfully even obtain from the physician a binding commitment to prescribe it," it was not plainly erroneous for DOL to conclude that the employee has not in any sense within the meaning of the statute or

regulations "made a sale." *Novartis*, 611 F.3d at 155 (App. C at 71a-72a). The court's conclusion is error.[3]

A. The court erred in its reliance on DOL's interpretation of the regulations

In interpreting the FLSA's outside sales exemption, the Court starts "as always, with the language of the statute." *Dean v. United States*, 129 S. Ct. 1849, 1853 (2009) (internal quotation marks omitted). At issue in this case is the meaning of the word "sale," which the statute defines to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k) (App. E at 80a).

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[3] The law prohibiting pharmaceutical sales representatives from engaging in a direct exchange of drugs for consideration, the FDCA and its accompanying regulations, was enacted for the benefit and protection of consumers. That law has nothing to do with the classification of pharmaceutical sales representatives as exempt outside salespersons under the FLSA or whether the duties assigned to pharmaceutical sales representatives are properly classified as exempt. By imposing a new technical requirement under the FLSA that there must be a consummated transaction to constitute a "sale" while relying upon the FDCA to demonstrate there can never be a sale, the Second Circuit and DOL are using the FDCA for purposes it was never intended to serve. Under the Secretary's interpretation, a regulatory scheme which is meant to protect consumers may ultimately result in a major upheaval of how the pharmaceutical industry classifies its employees and conducts its business — certainly an unintended consequence of the consumer protections afforded by the FDCA.

DOL began its argument, not with the language of the statute, but by relying upon the interpretative canon that FLSA exemptions must be construed narrowly. DOL Brief at 7 (App. M at 119a). The FLSA's definition of "sale," however, is not an exemption subject to the narrow construction canon. Rather, it is a statutory definition which is to be construed broadly, *see, e.g., Salyer v. Ohio Bureau of Workers' Comp.*, 83 F.3d 784, 786 (6th Cir. 1996), and which is, on its face, expansive.

Congress's use, for example, of the word "any" demonstrates that the listed examples should be interpreted broadly. *Ali v. Fed. Bureau of Prisons*, 128 S. Ct. 831, 835-36 (2008) ("the word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind'") (citations omitted). Beginning the definition with the same word, "sale," shows that the defined term is not restricted to a narrow, technical meaning. That conclusion is buttressed by Congress's election to define the term "sale" to include any "*other disposition*." 29 U.S.C. § 203(k) (App. E at 80a) (emphasis added). This catch-all term forecloses the possibility that Congress intended a restricted meaning of the defined term "sale" by requiring certain unwritten technicalities like a "consummated" transaction.[4]

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[4] The use of the phrase "sale or other disposition" is used in other statutory contexts, such as the Gun Control Act of 1968, 18 U.S.C. § 922(a)(6). This Court, in *Huddleston v. United States*, 415 U.S. 814 (1974), considered whether a felon redeeming a firearm from a pawnshop was "acquiring" the firearm in violation of section 922(a)(6). Huddleston had argued that a redemptive transaction was not a "sale" from the

Contrary to DOL's argument and the Second Circuit's decision, a "binding" commitment or "consummated" transaction is not required to effect a "sale" under the regulations and in fact is contradicted by them. *See* 29 C.F.R. § 541.503(c) (employee makes sales if he or she "obtain[s] a commitment for * * * purchases" or "direct[s] efforts toward the consummation of a sale") (App. K at 87a). In the preamble to the regulations, the Department of Labor confirmed that neither "binding" commitments nor direct transactions need occur between salesperson and customer by explaining that an employee engages in "outside sales" work if "the employee, in some sense, has made sales," and noting that "obtaining a commitment to buy," is sufficient. 69 Fed. Reg. at 22162-63 (App. L at 105a). Directing efforts toward the consummation of a sale and obtaining a commitment for purchases are precisely what pharmaceutical sales representatives do.

The only way in which DOL could conclude that pharmaceutical sales representatives are not exempt outside salespersons was to impose a new and unwarranted requirement that the commitments

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perspective of the pawnbroker, and so could not be an "acquisition" with respect to the person redeeming the firearm. The Court disagreed and interpreted the inclusion of the phrase "other disposition" to mean that Congress intended the statute to encompass more than traditional "sales" which connote transfers of ownership and title. *Id.* at 820-21. The same argument is applicable here: including "other disposition" within the statutory definition of a sale contemplates a disposition separate and distinct from a traditional "sale" resulting in a transfer of ownership or title.

those salespersons obtain must now be legally binding. The Second Circuit's decision deferring to DOL simply ignores the reality present in pharmaceutical sales that physicians are the only customers capable of placing the order for a prescription drug and that the prescription serves as the order for disposition to the patient. The pharmaceutical salesperson directs his or her efforts to consummating a sale not only in "some sense" but also in the "only sense" possible in the pharmaceutical industry. The fact that those sales efforts result not in a direct exchange of a good for consideration but by a physician placing the order does not diminish in any way the conclusion that the employee's primary duty is "making sales".

B. The court erred in its analysis of the outside sales exemption as applied to the pharmaceutical industry

The Second Circuit's conclusion that pharmaceutical sales representatives do not "make sales" as defined under the FLSA is based upon DOL's argument that those employees only "promote" sales made by other persons:

> Novartis sells its drugs to wholesalers; the wholesalers then sell them to pharmacies; and the pharmacies ultimately sell the drugs to patients who have prescriptions for them. The Reps promote the drugs to the physicians; the Reps do not speak to the wholesalers or to the pharmacies or to the patients.

Novartis, 611 F.3d at 153-54 (App. C at 70a.)

That conclusion ignores the reality that the *only* customer who may place an order for pharmaceutical drugs is the physician. The flaw in the court's analysis is that no pharmaceutical company could sell its products to wholesalers or pharmacies or patients if physicians did not write prescriptions. Without the demand from physicians, there is no sale to a wholesaler or pharmacy.

The restrictive approach taken by the Second Circuit cannot be reconciled with that of the Eleventh Circuit in *Gregory v. First Title of America Inc.*, 555 F.3d 1300 (11th Cir. 2009). The *Gregory* court acknowledged it was to narrowly construe the white-collar exemptions, giving "due regard to the plain meaning of the statutory language and the intent of Congress." It was mindful, however, that "[t]o read the FLSA blindly, without appreciation for the social goals Congress sought, would also do violence to the FSLA's spirit." *Id.* at 1307 (internal quotation marks and citations omitted). The Second Circuit's refusal to do the same and to take into account the reality of the sales process in the pharmaceutical industry serves no goal of the FLSA.

In contrast, the Eleventh Circuit took the realities of the sales process in another industry into consideration in *Gregory*. There, the employee, a "marketing director," did not consummate direct transactions with customers of the employer title company. Rather, she was "tasked only with inducing realtors, brokers and lenders to begin referring their customers — the end user — on to First Title for title insurance services." 555 F.3d at 1303. Ultimately, the court concluded that although the marketing director *did not consummate* direct

transactions, she nonetheless qualified as an exempt outside salesperson because she was responsible for obtaining "orders" for title services. *Id.* at 1309-10. Like the employee in *Gregory*, there is "no intervening sales effort" between the efforts of pharmaceutical sales representatives and the "consummation" of the sale. Once the physician writes the prescription, the "selling" is complete. *See id.* at 1310. [5]

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[5] The other cases relied upon by the Second Circuit likewise fail to support its conclusion that pharmaceutical sales representatives do not qualify for the outside sales exemption. *Novartis*, 611 F.3d at 152-53 (App. C at 67a-68a). The civilian military recruiters in the first case, *Clements v. Serco, Inc.*, 530 F.3d 1224 (10th Cir. 2008), did not "sell" anything. *Serco* involved the solicitation of a commitment to *join* the military, *not* the solicitation of a commitment to *buy* goods, a commitment which ultimately characterizes pharmaceutical sales. Moreover, unlike the situation in *Serco* whereby military recruiters had to follow up on the recruitment efforts by civilian employees to "close" the "sale," pharmaceutical sales representatives do not identify prospective purchasers for other employees to approach with a sales pitch.

Wirtz v. Keystone Readers Service, Inc., 418 F.2d 249 (5th Cir. 1969), suffers from the same problem. There, student salespersons who promoted magazine subscriptions to prospective customers were followed by sales managers who actually explained payment plans, executed the contract and collected payment from the customer. 418 F.2d at 252. The student salespersons were found to be non-exempt because they promoted sales made by other employees. *Id.* at 261. The sales process in *Wirtz* simply is not on point; no one follows a pharmaceutical sales representative into physicians' offices to consummate a transaction or obtain a binding commitment.

Before DOL's appearance in the court below, the outside sales exemption did not impose a requirement that sales employees consummate direct transactions with their customers. Indeed, despite DOL's interpretation announced in *Novartis*, the Bureau of Labor Statistics' Occupational Outlook Handbook recently recognized pharmaceutical sales representatives as employees whose duties include "selling products" for wholesalers or manufacturers where technical or scientific knowledge is required. Dep't of Labor, BUREAU OF LABOR STATISTICS' OCCUPATIONAL OUTLOOK HANDBOOK (2010-2011 Edition), *available at* http://data.bls.gov/cgi-bin/print.pl/oco/ocos119.htm ("Handbook"). The Handbook further acknowledges that "sales representatives' primary duties are to make customers interested in their merchandise and to arrange the sale of that merchandise." *Id.*

The narrow and inflexible interpretation of sales taken by the Second Circuit and DOL in this case contradicts the statute, regulations, and established jurisprudence. The unambiguous statutory language, coupled with the nature of the transaction involved in pharmaceutical sales, compels the conclusion that pharmaceutical sales representatives meet the requirements of the FLSA's outside sales exemption. The Court should grant the petition to review the Second Circuit's erroneous decision.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

October 4, 2010

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 09-1945-cv

SUMMARY ORDER

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, and SHAWN JONES, on behalf of themselves and others similarly situated,

Plaintiff-Appellees,

v.

SCHERING CORPORATION,

Defendant-Appellant.

Affirmed.

Appeal from an order of the United States District Court for the District of Connecticut.

Attorneys and Law Firms

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brief), for Appellees.

Present: AMALYA L. KEARSE, PETER W. HALL, Circuit Judges, JED S. RAKOFF, District Judge.*

*1 ON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the order of said district court be and it hereby is AFFIRMED.

Defendant Schering Corporation ("Schering") appeals pursuant to 28 U.S.C. § 1292(b) from an order of the United States District Court for the District of Connecticut, Janet Bond Arterton, Judge, which denied its motion for summary judgment dismissing the claims of plaintiffs, pharmaceutical sales representatives ("Reps") formerly employed by Schering, for overtime pay under the Fair Labor Standards Act of 1938 ("FLSA"), 29 U.S.C. § 201 et seq. Schering moved for summary judgment, arguing that Reps fall within the FLSA's exemption for "outside salesm[e]n," 29 U.S .C. § 213(a)(1). In a ruling dated March 30, 2009, and reported at 604 F.Supp.2d 385, the district court denied Schering's motion, concluding that, because the Reps undisputedly do not sell or make sales as those terms are defined in the FLSA and the regulations promulgated thereunder by the Secretary of Labor,

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* Honorable Jed S. Rakoff, of the United States District Court for the Southern District of New York, sitting by designation.

the Reps fall outside the FLSA's outside sales employee exemption. In an order dated April 17, 2009, the district court certified its order denying summary judgment as worthy of an immediate appeal pursuant to § 1292(b). Schering petitioned this Court, as required by that section, for leave to appeal; we granted the petition and heard Schering's appeal in tandem with the appeal in In re Novartis Wage and Hour Litigation, No. 09-0437-cv. We assume the parties' familiarity with the remaining facts and procedural history of the case.

On appeal, Schering contends that the district court erred as a matter of law in determining that the Reps were not exempt outside salesmen. We disagree. The burden of proving that employees fall within an exemption from the FLSA overtime pay requirements is on the employer. See, e.g., Bilyou v. Dutchess Beer Distributors, Inc., 300 F.3d 217, 222 (2d Cir.2002). Reviewing the matter de novo, and taking the record in the light most favorable to the plaintiffs, see, e.g., Dillon v. Morano, 497 F.3d 247, 251 (2d Cir.2007), we conclude, for the reasons stated in the district court's well-reasoned ruling, see 604 F.Supp.2d at 395-403, that Schering did not meet its burden. Accordingly, we affirm the order denying summary judgment for the reasons stated in the district court's ruling and for the reasons stated in our opinion in In re Novartis Wage & Hour Litigation, No. 09-0437 (2d Cir. July 6, 2010), also issued today.

We have considered all of Schering's contentions on this appeal and have found them to be without merit. The order of the district court denying Schering's motion for summary judgment is affirmed, and the matter is remanded for further proceedings

not inconsistent with this order.

FOR THE COURT:

CATHERINE O'HAGAN WOLFE, Clerk of Court

Slip Op. (2010)

2010 WL 2669304

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

Civil No. 3:07cv233 (JBA)

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, AND SHAWN JONES, on behalf of themselves and others similarly situated,

Plaintiffs

v.

SCHERING CORPORATION,

Defendant

March 30, 2009

JANET BOND ARTERTON, Judge

*386 Andrew W. Skolnick, Brian J. Wheelin, David A. Slossberg, Hurwitz Sagarin Slossberg & Knuff LLC, Milford, CT, Charles Joseph, Michael DiChiara, Michael D. Palmer, Joseph & Herzfeld LLP, New York, NY, Eric B. Kingsley, Kingsley & Kingsley APC, Encino, CA, Gregory N. Karasik, Ira Spiro, Spiro Moss Barness LLP, Los Angeles, CA, James A. Jones, Gillespie Rozen Watsky & Jones, P.C., Dallas, TX, for Plaintiffs.

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LLP, Florham Park, NJ, Richard Spehr, Mayer Brown LLP, New York, NY, Robert P. Davis, Mayer Brown LLP, Washington, DC, for Defendant.

RULING ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [Doc. # 85]

Plaintiffs Eugene Kuzinski, Marc Campano, Jerry Harris, and Shawn Jones (collectively, "Plaintiffs") initiated this suit against Schering Corporation ("Schering" or "Defendant"), their former employer, for relief from Defendant's alleged misclassification of them as "exempt" employees resulting in its failure to pay them overtime wages, in violation of the Fair Labor Standards Act (FLSA), 29 U.S.C. §§ 201 *et seq.* Defendant has moved for summary judgment on the ground that Plaintiffs fall within the FLSA's outside sales exemption. For the reasons set forth below, Defendant's motion for summary judgment is denied.

I. Factual Background

Schering manufactures and "sells prescription drugs to hospitals, certain managed care organizations, wholesale distributors and retail pharmacists." (Schering-Plough Corporation Form 10-K for Fiscal Year Ended Dec. 31, 2007, Ex. 1 to DiChiara 1st Decl. [Doc. # 97], at 18.) It employs sales representatives-alternately called Pharmaceutical Sales Representatives, Professional Sales Representatives, and Sales Representatives, to which positions the Court refers, collectively, as *387 pharmaceutical sales representative ("PSR")-through whom it "introduces and makes known its prescription drugs to physicians, pharmacists,

hospitals, managed care organizations and buying groups." (*Id.*) Schering previously employed each Plaintiff as a PSR.[1] According to Joseph DeFeo, Schering's Senior Director of Global Pharmaceutical Business Finance, PSRs are not responsible for promoting any Schering product that "can be sold without the use of a physicians prescription." (DeFeo Dep. at 55:10-14.)

Schering distributes its products to several entities: the bulk-"over 90 percent"-go to wholesalers, and the remainder go to governmental entities, hospitals, and directly to chain pharmacies.[2] According to DeFeo, wholesalers negotiate "inventory management agreements," which limit their inventory levels and set prices on Schering's products, with the "trade organization" and "legal team" operating under Schering's managed markets

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[1] Kuzinski 1st Decl. [Doc. # 96] at ¶ 2 (noting employment with Schering ended March 2006); Campano 1st Decl. [Doc. # 94] at ¶ 2 (noting employment with Schering ended July 2004); Harris 1st Decl., Ex. C to DiChiara 2d Decl. [Doc. # 103], at ¶ 2 (noting employment with Schering ended December 2006); Jones 1st Decl. [Doc. # 95] at ¶ 2 (noting employment with Schering ended September 2004).

[2] (DeFeo Dep. at 30:21-31:18 & 32:7-21 & 34:5-6.) DeFeo also testified that "[i]f there is an emergency order for a product that can't make its way through the supply chain of the pharmaceuticals, ... then the sale might be direct to ... maybe even a physician," who would purchase them though "a group purchasing organization" through which the physician would "receive the product directly but ... not directly pay[ ] for it." (DeFeo Dep. at 32:11-33:2.)

group. (DeFeo Dep. at 37:4-38:14; *see also* Abrahamsen Dep. at 47:7-23) (stating that managed markets group negotiates contracts.) A wholesaler may only negotiate the "price and quantity [of Schering products] supplied" when negotiating its inventory management agreements, and not with PSRs. Once an agreement is in place, under which a "wholesaler ... submit[s] an order though [Schering's] customer service group," that group fills the order after confirming that doing so would not leave the wholesaler with more of any product than is allowed under its inventory management agreement. (DeFeo Dep. at 37:4-22; *see also* Abrahamsen Dep. at 47:24-48:2 (stating that PSRs are not part of managed markets group).) PSRs are not "involved at all in reviewing the orders that come from wholesalers." (DeFeo Dep. at 39:18-21.)

Towards the end of each fiscal quarter, Schering's "customer service organization tracks shipments" and Schering "work[s] with our wholesalers to adjust the date the order may come in, to insure that it will get there on time," because the company records revenue when its product has been received by the wholesaler "purchasers." (DeFeo Dep. at 36:2-24.) Thus, Schering does not "record income when a health care provider tells a [PSR] that he or she will consider using a Schering product or prescribing a Schering product," or "promises a [PSR] that [he or she] will prescribe a Schering product," or "commits to a [PSR] that [he or she] will prescribe a Schering product," or writes a prescription for a Schering product. (DeFeo Dep. at 45:21-47:1.) It also does not record income when the "health care provider hands a prescription to a patient," or when the "prescription is filled at a

pharmacy," or "when a patient pays for a prescription at a pharmacy," or when "an insurance company reimburses a pharmacy for a prescription for a Schering product that is filled by a patient," or "when a [PSR] provides samples to a health care provider." ***388** (DeFeo Dep. at 47:2-20.) Instead, as the company has explained, it "recognizes revenue when title and risk of loss pass to the purchaser and when reliable estimates" of sales returns and the effects of discount and rebate arrangements and obligations "can be determined." (Schering-Plough Corporation Form 10-K for Fiscal Year Ended Dec. 31, 2007, at 117.)

Nonetheless, Schering's revenue for its prescription pharmaceuticals business depends on the use of its products by patients, which it turns requires physicians to prescribe its products. A physician's prescription-writing practices and Schering's sales are related in "a ripple effect up the supply chain," such that if physicians were to write fewer prescriptions or patients were to stop filling prescriptions written for Schering products, the demand for its products would reduce and Schering would experience lower sales to its wholesalers, whose inventory management agreements are designed to ensure that wholesalers' inventories "be as closely related to patient demand as possible." (DeFeo 42:11-43:3 & 54:9-55:23 & 57:14-58:5.) At oral argument Schering explained that its "drugs have been moving out the door because a patient showed up with a prescription from a physician who was influenced to write that prescription based on the information he was provided by the [PSR]." (Oral Arg. Tr. [Doc. # 125] at 6:18-7:17; *see also id.* at 15:23-17:20 & 40:13-41:15.)

To maintain or increase its market share, Schering promotes its products both through the work of PSRs and through direct-to-consumer advertising campaigns. DeFeo explained that direct-to-consumer campaigns drive expansions in the overall market for a type of pharmaceutical, and its PSRs' efforts "drive [Schering's] market share" for a given product. (DeFeo Dep. at 24:3-25:19.) Schering employs these promotional tools together with the expectation that their interaction will drive patient demand for its products, and thus increase its sales. (Abrahamsen Dep. at 26:4-16; *see generally id.* at 25:7-28:19; *see also* Lowy Dep. at 16:2-19:25 (describing Schering's budget for direct-to-consumer advertising campaigns for various products); Ciaffoni Dep. at 90:12-18 (noting Schering's desire to "achieve an optimal mix" between direct-to-consumer advertising, other media advertising, and PSRs' work).)

Each Plaintiff declares that as a PSR his "core job responsibility was to meet with medical professionals in an assigned territory to provide them with Schering-approved and carefully scripted information and materials about Schering's pharmaceutical products" with the intent that this data would "encourage the medical professionals to make Schering products available to patients, such as by recommending or prescribing them." Each Plaintiff worked away from Schering's offices throughout the day, visiting physicians, taking health care professionals to lunch or dinner at which they would promote Schering's products, and attending after-hours Schering training sessions and conferences with other Schering PSRs. Each Plaintiff reported to a District Manager, who supervised

Plaintiff's work and sometimes observed Plaintiff's fieldwork during "ridealongs." PSRs may not "relay any information to a health care provider other than what's been provided to them through training" by Schering, and may present only "preapproved clinical stud[ies]."[3] ***389** Schering purchases data about physicians' prescriptions, which it uses to "target" physicians-that is, select the physicians to whom PSRs will promote Schering products-and to track trends in the use of its products. (Abrahamsen Dep. at 18:4-19:23 (discussing vendors of prescription data); Kuzinski Dep. at 81:8-24 (explaining that he targeted physicians writing prescriptions for the class of drug he promoted).)

Schering PSRs' primary responsibility is to develop relationships with physicians and other health care professionals and deliver to them a "core message" about a particular pharmaceutical product manufactured by their employer to physicians with the intent that this message will persuade physicians to prescribe products made by Schering

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[3] Kuzinski 2d Decl. ¶ 7 & 9-10; *see also* Jones 2d Decl. ¶ 7 & 9-10 (same), Harris 2d Decl. ¶ 7 & 9-10 (same) & Campano 2d Decl. ¶ 7 & 9-10 (same), all at Ex. 9 to DiChiara 1st Decl. [Doc. # 97]; *see also* Ciaffoni Dep. at 35:12-25 (describing ridealongs); Granowitz Dep. at 36:3-33:10 (discussing limits on information presented by PSRs); Jones Dep. at 34:4-36:7 & 55:25-59:6 (describing ridealongs); Kuzinski Dep. at 100:22-101:25 (stating that he communicated with his District Manager at least once per week, and that she did two-day ridealongs with him once or twice per quarter); Harris Dep. at 29:11-32:2 (describing training).

rather than its competitors when their use is indicated. (*See* Ciaffoni Dep. at 18:10-21:13 & 28:5-34:19 & 83:15-85:11.) Before meeting with physicians PSRs create "pre-call plan[s]," which they create primarily by reference to what they know about the physicians they visit and Schering's up-to-date information about the product they promote. They receive substantial medical training from Schering, which they use in answering physicians' questions about the promoted product's indications, contraindications, effects, and other features. (*See id.*; Jones Dep. at 30:19-34:3 (describing medical and skills training) & 71:18-74:12 (describing data sources for pre-call plan).)

Sometimes PSRs begin their presentations with an "opening statement" about the product to engage the physician; in all visits they "are expected and required to sell [Schering] products within the approved promotional guidelines" and "are free to communicate any approved information in line with the labeling of [Schering] products to a physician," as provided to them by Schering. (Ciaffoni Dep. at 18:10-19:19 & 28:11-21 & 72:13-73:19.) Schering's Senior Director of Global Business Analytics, Glenn Abrahamsen, explained PSRs' work, sometimes referred to as "detailing," as being "the conversation that a [PSR] has with the physician during the engagement in that physician's office [during which] the [PSR] is there selling the various aspects of the product to the physician, answering the physician's questions and so on." (Abrahamsen Dep. at 79:16-

24.)[4] PSRs also understand that they are limited by regulations promulgated by the Food and Drug Administration ("FDA") in what they can tell physicians about their products. (*See, e.g.*, Jones Dep. at 46:22-47:17; Harris Dep. at 59:17-60:4.) Plaintiffs' visits with physicians were very short; Jones testified that they lasted no longer than five minutes. (Jones Dep. at 43:5-44:14.)

For their work Schering's PSRs earn, in addition to their base salary, incentive payments based, roughly, on the number of prescriptions for Schering products written ***390** in the geographic area over which they have jurisdiction. "[D]irect links are [not] made" between a PSR's work and a physician's prescription for a Schering product (and, thus, to resultant increases in Schering's market share), and Schering does not establish a "one-to-one relationship" between them. Moreover, in many cases "[PSRs] work collaboratively" and in tandem with direct-to-consumer advertising campaigns, which makes specific attribution impossible. Nonetheless, a Schering PSR earns commissions on

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[4] At oral argument Schering stated that PSRs' "job is to tell the physician about the attributes and any contraindications, the uses, the benefits of those drugs, and if the doctor raises questions about a competitor, to respond to those and explain why the drugs are different. They cannot say to the doctor, 'I can sell you Avelox for $5 a tablet' because they're barred by law from doing that, but everything else they do is aimed at convincing the physician that the right thing to do is to write a prescription for the appropriate patient class." (Oral Arg. Tr. at 12:22-13:7.)

the basis of "the number of prescriptions that are attributed to [her]" and where appropriate PSRs "share credit" for such prescriptions. (Abrahamsen Dep. at 57:2-68:14 & 85:5-20; *see also* McDermott Dep. at 23:4-13 (stating that District Managers also receive incentive compensation) & 34:15-23 (discussing incentive and salary components of PSRs' compensation); Email from Carrie Cox Connect dated Dec. 23, 2004, Ex. B43 to Def.'s Mem. Supp. Mot. Summ. J. [Doc. # 86] (describing 2005 Incentive Compensation Plan for Schering PSRs).) Schering classified Plaintiffs as exempt from FLSA's overtime pay requirements.

It is undisputed that both Schering and other companies in the pharmaceutical industry use the term "sales" to portray the work that PSRs do, and that that term permeates both Schering's and its employees'-including Plaintiffs'-description of the work of promoting Schering's products. Not only does Schering name the PSR position a sales position and consider its promotional activities "selling," but its advertisements seek individuals with sales skills and experience,[5] and it evaluates its PSRs "on their sales performance" and "on their selling skills."[6] Plaintiffs also utilized the term "sales,"[7] and in fact, as their

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[5] *See, e.g.*, Job Advertisement; Job Level Description for Virology Sales Representatives and Sales Associates; Participant's Workbook (describing "The Schering-Plough Selling Process"), Exs. B9 & B14-B15 & B19-B20 to Def.'s Mem. Supp.

[6] McDermott Dep. at 17:23-18:3.

[7] *See, e.g.*, Campano Job Application (listing "Professional

job descriptions indicate, they were each employed as "sales representatives."[8] Beverley Rowley, a self-

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Sales Representation" as position sought); Harris Job Application (listing "Sales Representative" as position sought); Jones Job Application (listing "Sales-Hepatitis C" as position sought); Campano Resume (including objective as being continuation of "successful career as a Professional Pharmaceutical Sales Representative" and listing former employment as Schering PSR as including achievement of "maintenance and growth of market share"); Jones Resume (listing "Products Sold" while employed as "Pharmaceutical Specialist"); Harris Application Letter (noting his "firm grasp of advanced clinical sales technique and strong communication and marketing skills"), Exs. B3-B5 & B11-13 to Def.'s Mem. Supp.; *see also* Jones Dep. at 50:21-53:10 (noting that as a PSR for another pharmaceutical company Jones did not "actually sell, have in [his] hands, drugs from [the former employer] that the doctors bought from [him]" but described himself as performing sales because "I believed I was doing a good job of promoting the products" and sought a similar position with Schering).

[8] Offer Letter to Campano (hiring Campano as "Professional Sales Representative"); Offer Letter to Harris (hiring Harris as "Oncology/Biotech Sales Representative"); Offer Letter to Jones (hiring Jones as "Hepatitis Sales Representative"), Kuzinski Retirement Letter (noting retirement as "sales representative"), Exs. B31-33 & B36 to Def.'s Mem. Supp; *see also* Jones Dep. at 30:10-18 ("I was hired into Schering's sales force.... I do understand that Schering considered the job to be a sales position."); Kuzinski Dep. at 28:23-29:14 (noting that in a previous job "it was definitely-[I was] selling" because "we made pharmacy calls and sold

described "medical behavioral scientist," testified that physicians ***391** call PSRs "sales reps" and "see them as people who are selling their particular product." (Rowley Dep. at 79:1-9; *see also* Rowley CV, Ex. B40 to Def.'s Mem. Supp.) One Schering executive described PSRs' work as sales, and also sometimes referred to the health care providers to whom PSRs presented information as "customers,"[9] but stated that he used the verbs *promote and sell* "interchangeably" because "[t]hey mean the same thing" and to him there is no "distinction between promoting a product and selling a product" in the pharmaceutical industry. (Granowitz Dep. at 108:1-12.) Kuzinski testified that he considered himself to be selling "[e]ven though the doctor wasn't buying the drug from [him]" because he was "getting [the doctor] to recommend your product versus the competition," and "in [Kuzinski's] mind that was a sale." (Kuzinski Dep. at 29:15-30:3.)

It is also undisputed that both Schering and Plaintiffs use the term "commitment" to describe what they hoped to obtain from a physician during a visit. Jones testified that "[t]he ultimate goal in pharma is to obtain a verbal commitment," but that he "did not get a verbal commitment" even though he

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directly to the pharmacists. And at that time there were ma and pa pharmacies. Now you have all chains; ma and pa's have gone by the wayside.").

[9] Granowitz Dep. at 47:18-48:16 & 86:10-87:2; *see also* Ciaffoni Dep. at 18:10-21:6 (describing various health care professionals to whom PSRs promote Schering products as "customers").

"establish[ed] a strong relationship with the physicians, office staff, and nurses" at a particular health care facility. (Jones Dep. at 217:12-24.) Harris testified that although it was expected of him, he did not feel comfortable asking physicians for commitments to write prescriptions. (Harris Dep. at 62:16-63:1.) He further testified that he considered his job as being "[t]o educate [physicians] and hopefully put [Schering's] products in a favorable light," and while he agreed that "the ultimate goal [was] to influence [physicians] to write more prescriptions for the products," he stated that "[w]e just never knew if that was accomplished" because his job involved

> a theoretical promotion. The people that bought the drugs were not the people we were talking to. Those were the consumers. We were talking to physicians, and physicians made prescribing decisions based on a great deal of data, including peer information, journal information, [and] publications of a medical nature.

(Harris Dep. at 20:24-21:18.)

Nonetheless, notwithstanding the industry terminology used by Plaintiffs and their employer, it is also undisputed that during their visits with physicians Schering's PSRs do not enter into contracts with physicians over the price or quantity of Schering's products, obtain their orders for Schering's products, or get binding commitments from the physicians to purchase or prescribe Schering's products. Each Plaintiff declared:

> I did not enter into contracts or obtain binding commitments from physicians that

> they would prescribe Schering products in the future. Moreover, I did not receive any guarantee from the doctor that they would prescribe the products to patients in the future.... Schering told [PSRs] to ask for a 'commitment' from a physician to prescribe Schering products; nevertheless, even if the physician did give a commitment, it was not binding.... Physicians were free to do as they chose and they would frequently end up not prescribing the products.

(Kuzinski 1st Decl. [Doc. # 96] at ¶ 10; Campano 1st Decl. [Doc. # 94] at ¶ 10; Harris 1st Decl., Ex. C to DiChiara 2d ***392** Decl. [Doc. # 103], at ¶ 10; Jones 1st Decl. [Doc. # 95] at ¶ 9.)

Plaintiffs' descriptions of the non-binding nature of these commitments comports with Schering executives' descriptions of PSRs' work. One of Defendant's Vice Presidents testified that PSRs "do not enter into contract discussions" under any circumstances. (Granowitz Dep. at 44:18-22.). They do not negotiate contracts or product pricing with physicians, or give them pharmaceutical products in exchange for money or other consideration. Physicians do not order drugs through PSRs, and in fact do not order products from anyone at Schering even in the "emergency situations" described above. PSRs do not ever exchange money for these products. As Abrahamsen explained:

> Q. ... Now, we may debate the semantics of the question but the pharmaceutical reps don't sell anything directly to the physicians, correct?
>
> ...

> A. Do you mean do the representatives dispense the product at the point of sale to the physicians, is that what you are referring to?
>
> Q. Yes.
>
> A. No, they do not dispense, they do not carry the products in their bag to sell directly to physicians.
>
> Q. So, the sales information that, your department uses to determine targeting and alignments and field force sizing, that is based on sales that occur at the pharmacies, correct?
>
> A. Yes, sales adjudicated at the pharmacies, yes.

(Abrahamsen Dep. at 68:15-69:21.) Each Plaintiff described his job duties in a manner similar to Abrahamsen. Each declared:

> Throughout my employment with Schering, I never sold any Schering products or services to physicians, drug wholesalers, retail pharmacies, or anyone else. I never took orders for Schering products or services. I never negotiated prices for Schering products or services. I never collected money for Schering products or services. I never formed contracts for Schering products or services. The physicians to whom I provided information about Schering products did not purchase Schering products through me, nor did these physicians purchase these products for their patients. I did not promote Schering products directly to patients or end-users. My

> job duties at Schering did not include meeting, communicating, or interacting with, or gathering information about, Schering's wholesale and retail customers in any way.

(Kuzinski 1st Decl. [Doc. # 96] at ¶ 8; Campano 1st Decl. [Doc. # 94] at ¶ 8; Harris 1st Decl., Ex. C to DiChiara 2d Decl., at ¶ 8; Jones 1st Decl. [Doc. # 95] at ¶ 7.)

Rowley's testimony was consistent with Plaintiffs' declarations and the Schering executives' testimony. She testified that there is no "money exchanged between a physician and a sales rep" and that having reviewed Schering's training materials, she could confirm that Schering does not train its PSRs to "negotiate prices for their pharmaceutical products" or "enter into contracts with physicians" or take "orders" from physicians in the form "a physician wants X amount of a particular product." (Rowley Dep. at 77:13-22 & 100:9-101:5.) Nor, according to Rowley, was this surprising. She stated that not only is it unlawful for a physician to purchase pharmaceutical products from its PSRs, but due to their ethical obligation to "prescribe a product" only if it is in "the best interests of their patients," physicians can make only non-binding commitments to a PSR to prescribe a particular product. (Rowley Dep. at 46:25-47:4 & 98:7-20.) At oral argument Schering conceded "that ***393** [PSRs] do not participate in transferring product from Schering Corp[.] to the distributors or to wholesalers or to retail locations" or to any other entity, and in fact "they're prohibited by law from doing so." (Oral Arg. Tr. at 6:9-16.)

II. Summary Judgment

Summary judgment is appropriate where the record after discovery "show[s] that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). An issue of fact is "material" if it "might affect the outcome of the suit under the governing law," and is "genuine" if it could lead "a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). In moving for summary judgment against a party who will bear the ultimate burden of proof at trial, the movant "need not prove a negative," but "need only point to an absence of proof on plaintiff's part, and, at that point, plaintiff must 'designate specific facts showing that there is a genuine issue for trial.' " *Parker v. Sony Pictures Entm't, Inc.*, 260 F.3d 100, 111 (2d Cir.2001) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986)). If the record as a whole, viewed in the light most favorable to the nonmoving party, "could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial," and summary judgment should follow. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986) (quotation marks omitted).

III. The FLSA Outside Sales Exemption

A. Legal Principles

This Court analyzed the outside sales exemption to employers' obligation under the FLSA to pay overtime wages to their employees in the context of PSRs employed by pharmaceutical companies in

Ruggeri v. Boehringer Ingelheim Pharmaceuticals, Inc., 585 F.Supp.2d 254 (D.Conn.2008) ("*Ruggeri I* ") (denying summary judgment to pharmaceutical company on outside sales and administrative exemptions, and granting summary judgment to plaintiffs as to outside sales exemption) and *Ruggeri v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 585 F.Supp.2d 308 (D.Conn.2008) ("*Ruggeri II* ") (denying Defendant's motion for interlocutory appeal of ruling as to outside sales exemption).

First, the Court observed that "[e]xemptions to the FLSA's overtime requirement are to be 'narrowly construed against the employers seeking to assert them and their application limited to those establishments *plainly and unmistakably* within their terms and spirit.' " *Ruggeri I*, 585 F.Supp.2d at 261 (quoting *Bilyou v. Dutchess Beer Distribs., Inc.*, 300 F.3d 217, 222 (2d Cir.2002) (quoting *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392, 80 S.Ct. 453, 4 L.Ed.2d 393 (1960))) (emphasis added in *Ruggeri I*).

Ruggeri I then concluded that application of the outside sales exemption to exempt employees from overtime pay required that the employees consummate sales or obtain contracts or orders. It explained:

> Employers are granted an exemption from the FLSA requirement that they pay overtime to "any employee employed ... in the capacity of outside salesman," with "such terms [to be] defined and delimited from time to time by regulations [.]" 29 U.S.C. § 213(a)(1). The FLSA defines the words "sale" or ***394** "sell" to "include[ ] any sale,

exchange, contract to sell, consignment for sale, shipment for sale, or other disposition," § 203(k), and regulations promulgated by the Department of Labor ("DOL")[10] specify that this includes "the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property," 29 C.F.R. § 541.501(b). Under DOL regulations, the outside sales exemption applies to

> any employee: (1) Whose primary duty is: (i) making sales within the meaning of section [203(k)], *or* (ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer; *and* (2) Who is customarily and regularly engaged away from the employer's place or places of business in performing such primary duty.

29 C.F.R. § 541.500(a) (paragraph breaks omitted). The regulation itself thus dictates that if employees do not make any sales and do not obtain any orders or contracts, then they cannot fit within the outside sales exemption, because such work must be their "primary duty." *See also* 29 C.F.R. §

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[10] The Department of Labor's regulations "have the force of law," and "are to be given controlling weight unless they are found to be arbitrary, capricious, or manifestly contrary" to the FLSA. *Freeman v. Nat'l Broad. Co., Inc.*, 80 F.3d 78, 82 (2d Cir.1996).

541.503(a) (Even though promotional work can be considered exempt sales work, "promotional work that is incidental to sales made, or to be made, *by someone else* is not exempt outside sales work") (emphasis added). If the employees make at least some sales or obtain at least some orders or contracts, then the outside sales exemption *may* apply, provided that such work constitutes the employees' "primary duty."

DOL regulations clarify what it means for an employee's work to be her "primary duty": such work must be "the principal, main, major or most important duty that the employee performs." § 541.700(a). While "[t]he amount of time spent performing exempt work can be a useful guide in determining whether exempt work is the primary duty of an employee," § 541.700(b), the "[d]etermination of an employee's primary duty must be based on all the facts in a particular case, with the major emphasis on the character of the employee's job as a whole," § 541.700(a).

In addition, when determining what work performed by employees is exempt outside sales, all work that is "incidental to and in conjunction with the employee's own outside sales or solicitations" as well as "work that furthers the employee's sales efforts" must also be considered exempt outside sales. § 541.500(b). At this point in the inquiry, an employer seeking to establish that its employee's primary duty is exempt outside sales work may demonstrate that her other

> work is "incidental to and in conjunction with" her sales work by pointing to the indicia of sales surrounding that other work. This indicia-of-sales inquiry, however, is limited to circumstances where the employee actually makes sales, and the question is whether her consummation of sales, plus her work "incidental to and in conjunction with" such consummation, is sufficient to deem sales her "primary duty." *See, e.g., Ackerman v. Coca-Cola Enters., Inc.*, 179 F.3d 1260, 1265 (10th Cir.1999) ("[I]f the employee in question does not actually consummate the sale at the location in question, then his other activities, even if closely related to sales, are not 'incidental to ***395** and in conjunction with' those sales under the regulations.").

Ruggeri I, 585 F.Supp.2d at 261-62 (alterations in *Ruggeri I*); *see also Ruggeri II*, 585 F.Supp.2d at 311-19.

B. Discussion

Based on this view of the outside sales exemption's contours described above, the Court held that Boehringer's PSRs did not fit within the outside sales exemption because they did not "make sales or obtain contracts or orders," as required under the regulations. *Id.* at 272; *accord Smith v. Johnson & Johnson*, No. 06-4787(JLL), 2008 WL 5427802, *4-*7, 2005 U.S. Dist. LEXIS 104952, *11-*21 (D.N.J. Dec. 30, 2008) (citing *Ruggeri I* and *Ruggeri II* and holding that a PSR is not an outside salesperson under the FLSA); *id.*, 2008 WL 5427802, *7, 2005 U.S. Dist. LEXIS 104952, *21 (explaining that it

"does not find that the regulations necessarily require consummation of a sale in the traditional sense of a signed order for delivery of services or goods. But the regulations do require more than nonbinding declarations of intent to prescribe in response to promotional inducements of the kind offered by [the PSR] in this case.").

The same conclusion the Court reached in *Ruggeri* as to Boehringer's PSRs applies here given the material similarities between the duties performed by Schering's PSRs and Boehringer's PSRs. Like Schering's PSRs, Boehringer's PSRs make visits to physicians that "do not culminate in physicians entering into contracts to write a particular number of prescriptions, as PSRs are forbidden by Boehringer from negotiating such contracts." *Ruggeri I,* 585 F.Supp.2d at 260. Like Schering's PSRs, Boehringer's PSRs "do not sell Boehringer's products in question directly to patients, as it is unlawful to dispense them without a physician's prescription." *Id.*

Moreover, Defendant presents arguments that echo those which this Court rejected in *Ruggeri.* Schering argues that "[t]he physician is an indispensable party to the sale of prescription pharmaceuticals given the mandatory regulations applicable to the pharmaceutical industry. Such regulations make the transaction no less of a sales transaction; it is what a sale looks like in this highly regulated industry." (Def.'s Mem. Supp. at 5.) As this Court explained in *Ruggeri I,* this argument is unavailing:

> The justification for the pharmaceutical industry's use of PSRs and direction of their

> efforts at physicians based on the artifact of medical and drug regulation pointed out by Defendant does not provide justification for applying the outside sales exemption to Plaintiffs, especially given that FLSA exemptions apply only to those employees who are "plainly and unmistakably within" them. *Bilyou,* 300 F.3d at 222.

Ruggeri I, 585 F.Supp.2d at 267.

Defendant also argues that employees can be held to fall within the outside sales exemption on the strength of an indicia-of-sales analysis (styled a " 'totality-of-the-circumstances' analysis") even where they do not actually consummate sales or obtain orders or contracts. (*See, e.g.,* Def.'s Mem. Supp. at 4.) This Court rejected that construction of the exemption as contrary to the text of the regulations themselves, which expressly state that employees who do not "mak[e] sales or obtain[ ] orders or contracts" cannot fall within the outside sales exemption. *Ruggeri I,* 585 F.Supp.2d at 267-68 & n. 6; *Ruggeri II,* 585 F.Supp.2d at 311-19.

Because Schering's PSRs do not make sales or obtain orders or contracts, the outside sales exemption is inapplicable to ***396** them. Recent cases on which Defendant relies do not persuade this Court that either its construction of the outside sales exemption or its conclusion that Schering's PSRs fall outside that exemption was in error.

In *In re Novartis Wage and Hour Litig.,* 593 F.Supp.2d 637 (S.D.N.Y.2009), which determined that PSRs fall within the FLSA's outside sales exemption, the court concluded that the "rationale behind the outside sales exemption" is to exclude

from the FLSA's overtime protections employees who "(1) generate commissions for themselves through their work and (2) work with minimal supervision, making adherence to an hours-based compensation scheme impractical," rather than employees who " 'sell,' as that term is technically defined." *Id.* at 648-49 (discussing *Jewel Tea Co. v. Williams,* 118 F.2d 202, 207-08 (10th Cir.1941)). Rejecting the plaintiffs' argument that PSRs promoted but did not "sell" pharmaceutical products to physicians,[11] the court explained that it

> cannot ignore reality. Distributors are not the end-users of NPC's products. If physicians did not prescribe NPC products, patients would be unable to buy them and distributors would have no incentive to make purchases from NPC. The purchase cycle commences with a prescription from physicians, who are therefore the appropriate target of the [PSRs'] sales efforts. When the physician writes a prescription for the NPC

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[11] As here, the defendant pharmaceutical company Novartis Pharmaceuticals Corporation ("NPC") employed PSRs to promote its products to physicians whom it had targeted; the PSRs' promotional activities included the delivery of "a 'core message' about NPC products to each physician they visit" as well as sample products, but because "[u]nder applicable FDA regulations, [PSRs] are barred from selling NPC drugs directly to physicians," PSRs instead seek to "persuad[e] physicians to write prescriptions that are ultimately used by patients in order to obtain NPC products from a pharmacy." *In re Novartis,* 593 F.Supp.2d at 642-43.

> product, then a sale can take place. Without prescriptions, patients cannot buy the drugs and there is no sale.

Id. at 650-51.

The court further examined the ways in which statutory and regulatory restrictions affect pharmaceutical companies' sales practices. Observing that "[t]he FDA regulates the pharmaceutical industry in myriad ways, controlling, among other things, how drugs may be researched, manufactured, labeled, sold, distributed, and prescribed," the court explained that while "physicians have an ethical obligation to prescribe only drugs suitable for their patients' medical needs," which precludes them from entering into binding commitments with PSRs, "the physicians called upon by [PSRs] ultimately control the purchase of NPC products by writing prescriptions." *Id.* at 650. It concluded that "[g]iven the FDA's regiment controlling how drugs are sold and delivered to patients, it is clear that [PSRs] do not pave the way for sales that will be made by others," but rather that they make their own sales. *Id.* at 652. It held:

> [R]ecognizing the realities of the pharmaceutical industry is not incompatible with engaging in a narrow reading. To the contrary, it produces results that reflect the exemption's terms and spirit. [PSRs] make sales by obtaining commitments to prescribe NPC drugs from physicians. They are credited with those sales and compensated accordingly by means of incentive payments. They also work free of direct supervision. As such, ... they qualify as exempt outside

salespersons.

***397** *Id.* at 653. This conclusion, it explained, comports with application of the exemption because given PSRs' job duties, "the logical conclusion" is that "[PSRs] make sales in the sense that sales are made in the pharmaceutical industry." *Id.* at 650.

In reaching its conclusion that PSRs fall within the exemption, the *In re Novartis* court distinguished the case of non-exempt employees who "promoted magazine subscriptions by going door-to-door and persuading customers to fill out a non-binding order card," pursuant to which managers would call on those customers and persuade them to subscribe. *Id.* at 653 (discussing *Wirtz v. Keystone Readers Serv., Inc.,* 418 F.2d 249, 252 (5th Cir.1969)). Unlike that case, it held, "there are no other [Novartis] employees who consummate sales whose foundations were laid by the [PSRs]," and the PSRs are credited with any prescriptions written for Novartis drugs "[t]o the extent the [ ] physicians [called on by PSRs] write prescriptions for [Novartis] drugs." *Id.* at 653.

This Court finds the analysis underpinning *In re Novartis* unpersuasive for the following reasons. The regulations governing the outside sales exemption not only require an exempt employee to make sales, but also define what a "sale" is. And the act of making a "sale," as that term is defined by the FLSA and DOL regulations, is a prerequisite to falling within the outside sales exemption. *See Clements v. Serco,* 530 F.3d 1224, 1227 (10th Cir.2008) (civilian military recruiters employed by company in contract with U.S. Army are not within the outside salesperson exemption where they "engaged in sales training and 'sold' the idea of joining the Army to

potential recruits [because they] did not engage in sales work as defined by the Department of Labor regulations."). The Second Circuit has observed that "[g]iven the broad scope of the FLSA and its implementing regulations," the DOL's "regulations provide only general guidance to accommodate the varying needs of employers and employees in a diverse and varied national economy." *Havey v. Homebound Mortgage, Inc.*, 547 F.3d 158, 163 (2d Cir.2008) (citing *Acs v. Detroit Edison Co.*, 444 F.3d 763, 770 (6th Cir.2006)). That observation, however, does not mean that an exemption to an employer's obligation to pay overtime under the FLSA can apply more broadly than "[t]he regulations specify." *Id.*; *see also id.* at 163-64 (describing the contours of the administrative exemption by reference to the text of the DOL's regulations following this observation about their "scope" and "general guidance"); *Amendola*, 558 F.Supp.2d at 470 ("As a starting point, the interpretation of the [FLSA outside sales] exemption rests on the plain meaning of the statutory and regulatory texts that define it."). This is especially so in light of the requirement that exemptions from the FLSA's overtime requirement be " 'narrowly construed against the employers seeking to assert them and their application limited to those establishments plainly and unmistakably within their terms and spirit,' " with "[t]he burden of invoking these exemptions rest[ing] upon the employer." *Bilyou v. Dutchess Beer Distribs., Inc.*, 300 F.3d 217, 222 (2d Cir.2002) (quoting *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392, 80 S.Ct. 453, 4 L.Ed.2d 393 (1960)) (emphasis added); *see also Havey*, 547 F.3d at 163 (repeating employer's burden and rule of narrow construction of FLSA exemptions) (quoting *Martin v. Malcolm Pirnie, Inc.*, 949 F.2d

611, 614 (2d Cir.1991)). Therefore, while the "reality" may be that "[d]istributors are not the end-users of [pharmaceutical ***398** companies'] products,"[12] that fact is irrelevant to the dispositive inquiry of whether PSRs "mak[e] sales" of those products as defined in the FLSA.

Under the FLSA, the term " '[s]ale' or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition," 29 U.S.C. § 203(k), and also "include[s] the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property," 29 C.F.R. § 541.501(b). Schering's PSRs do not make, or engage in, any of these things. PSRs do not consummate or make any "sales" of pharmaceuticals to the physicians they visit. PSRs do not "exchange" with physicians for any drugs; they do not make any "contract[s] to sell" drugs to physicians; they do not make any "consignment for sale" with physicians;[13] they do not make any "shipment[s] for sale" to physicians; and they do not make any "other disposition" of drugs with physicians.[14] PSRs also do not "transfer

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[12] *In re Novartis,* 593 F.Supp.2d at 650.

[13] That is, PSRs do not "commit," "dedicate," "deliver," "transfer," "give" or "hand over possession" drugs into the physicians' "custody," or "entrust" drugs to physicians, for a later sale. *See* BLACK'S LAW DICTIONARY 327 (8th ed. 2004) (defining "consign" and "consignment"); WEBSTER'S II DICTIONARY 157 (3d ed. 2005) (same).

[14] Plaintiffs did not "transfer[ ] something to [a physician's]

[pharmaceuticals] for a price." *Cf.* BLACK'S LAW DICTIONARY 1364 (8th ed. 2004) (defining "sale").

Moreover, PSRs and physicians do not even have the capacity to consummate sales. Schering's PSRs, like Boehringer's PSRs, are barred both by law and by their employer from entering into contracts or binding commitments with physicians for the prescription of their employer's products. *Cf. Ruggeri I,* 585 F.Supp.2d at 267-68 (PSRs "do not and cannot make or produce" sales); *accord Smith,* 2008 WL 5427802, *7, 2008 U.S. Dist. LEXIS 104952, *20-*21 ("in no ordinary sense of the word 'consummation' could one of [the PSR's] sales calls end in the consummation of a sale. [The PSR] could only provide useful information to the physician, and could not enter into an agreement regarding

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care or possession" including "by deed or will," and they did not engage in the "relinquishment of property" to physicians. *See* BLACK'S LAW DICTIONARY 505 (8th ed. 2004) (defining "disposition"). Given this meaning of "disposition," Defendant's argument that the regulation's catch-all term "other disposition" encompasses in its scope activities such as those performed by Plaintiffs is unavailing. Were the Court to construe the phrase "other disposition" broadly enough to encompass PSRs' visits with physicians (*see* Def.'s Mem. Supp. at 22 (emphasizing phrase); Oral Arg. Tr. at 40:5-41:15 (Schering arguing that the phrase "allow[s] for those instances where there cannot be a direct interaction between the salesman and the purchaser")), it would substantially expand the outside sales exemption, in direct contravention of its mandate to construe the exemption narrowly and within its plain terms.

prescriptions by the physician."). And physicians neither have nor exercise the capacity to make binding commitments to purchase or prescribe pharmaceuticals promoted by Schering's PSRs. DeFeo testified that physicians never order pharmaceuticals directly from Schering even in potential "emergency" situations, when they would obtain them directly through a "group purchasing organization," and in any event ethical and legal obligations bar physicians from "mak[ing] a binding commitment to a [PSR] to prescribe certain [pharmaceutical] products." *In re Novartis,* 593 F.Supp.2d at 650; *see also Ruggeri I,* 585 F.Supp.2d at 268 ("physicians do not have 'the capacity to purchase or place an order for' ... pharmaceutical products").

***399** The conclusion that PSRs fall within the outside sales exemption from FLSA's overtime provisions on the basis of "the characteristics of the industry in question," *In re Novartis,* 593 F.Supp.2d at 649, "[n]otwithstanding PSRs' lack of capacity to sell, and physicians' lack of capacity to purchase," *see Ruggeri I,* 585 F.Supp.2d at 268, appears to be the back-fitting of the FLSA to industry practices which this Court has rejected, *see id.* at 272; *see also Clements,* 530 F.3d at 1227 ("[t]he touchstone for making a sale, under the Federal Regulations, is obtaining a commitment."); *Smith,* 2008 WL 5427802, *7, 2008 U.S. Dist. LEXIS 104952, *19 ("[p]hysicians ... do indeed present a chokepoint in the sale of pharmaceuticals, but the nature of the prescription system insulates them from being amenable to 'sales' within the definition of the applicable regulation"). *In re Novartis*'s focus on a pharmaceutical product's "purchase cycle," which

"commences" with a physician writing a prescription for the product for a patient, *In re Novartis*, 593 F.Supp.2d at 650-51, and which, in this case, presumably would continue through a patient's filling the prescription at a pharmacy, to the pharmacy's re-ordering the product from a wholesaler, who then places an order for additional product with the "trade organization" and "legal team" operating under Schering's managed markets group, is not what the PSRs do, which excludes it from the relevant inquiry for FLSA purposes.

As DeFeo's testimony and Plaintiffs' declarations illustrate, the closest that Schering's PSRs come to consummating "sales" is increasing the overall demand for its products, such that *non-PSR* Schering employees negotiate and commit to contracts with wholesalers-*not* the physicians to whom Schering's products are promoted. An employee does not consummate a "sale" for purposes of the FLSA merely by "lay[ing] the groundwork" for another employee to obtain a customer's commitment. *Clements*, 530 F.3d at 1229; 29 C.F.R. § 541.503(a) (even though promotional work can be considered exempt sales work, "promotional work that is incidental to sales made, or to be made, *by someone else* is not exempt outside sales work") (emphasis added). Here, not only do the PSRs not consummate the sales, but the physicians with whom the PSRs visit are not Schering's customers. To the extent PSRs lay foundation or groundwork, it is to increase or maintain their employer's market share for the products they promote. In this sense they pave the way for sales but in no more direct a manner as a pharmaceutical company's direct-to-consumer advertising, which raises demand for that company's

products. Neither of these activities constitutes "sales" under the FLSA.

The Eleventh Circuit's decision in *Gregory v. First Title of America, Inc.* is not to the contrary. There, the court held that an insurer's "marketing executive" made sales-and thus was an exempt outside salesperson-because "[o]nce an order for title insurance services is obtained [by the plaintiff], the sale is complete." 555 F.3d 1300, 1309 (11th Cir.2009) (first alteration in original). The court relied on the fact that the plaintiff "did not collect orders and turn them over to another salesperson," and there was no "evidence of any other intervening sales effort between [the plaintiff] and orders placed with [the employer]," such that "[a]s opposed to conceiving of [the plaintiff] as 'paving the way' for others to consummate the sale, we view her as acting more as a conduit through which orders for services flowed." *Id.* The critical difference between the work of First Title's marketing executive and Schering's PSRs is obvious: whereas the marketing executive did all of the work necessary to reach an agreement with a ***400** customer, PSRs do not even communicate with the entities to which Schering sells its products, let alone negotiate the contracts or process the orders by which its products are sold.

Some courts concluding that PSRs "sell" pharmaceutical products within the meaning of the FLSA have looked to *IMS Health Inc. v. Ayotte,* 550 F.3d 42 (1st Cir.2008). There, the court was faced with a constitutional challenge to the Prescription Information Law, a New Hampshire statute affecting PSRs' work by preventing the use "'for any commercial purpose'" of information about pharmaceutical prescriptions containing any

"'patient-identifiable and prescriber-identifiable data.'" *Id.* at 47 (quoting N.H.Rev.Stat. Ann. § 318:47-f). In the course of lengthy opinions upholding the constitutionality of the law, both the majority and concurrence/dissent described generally the work of PSRs-in the First Circuit's parlance, "detailers"-within the pharmaceutical industry. The majority described each part of the state's evidence that its law "directly advances [its] interest" of "cost containment" as "forg[ing] some part of the causal chain leading from transfers of prescribers' histories for use in detailing to higher drug prices," *id.* at 55, and stated: "[d]etailing works: that it succeeds in inducing physicians to prescribe larger quantities of brand-name drugs seems clear (even if the exact magnitude of that effect is not)," *id.* at 56. In an opinion concurring and dissenting, one member of the panel used the word "sales" in describing the efficacy of PSRs' efforts: "Detailing is the face-to-face advocacy of a product by sales representatives who visit doctors' offices and hospitals to meet with the prescribing health care professionals. Although the objective of these visits is to make sales, detailers often provide valuable information about the drugs they are selling." *Id.* at 71 (Lipez, J., concurring and dissenting).

The question of "sales" of pharmaceuticals, whether under the FLSA or any other law, was not before the First Circuit, and neither the majority nor the concurrence/dissent in that case makes any reference to the FLSA. The focus of that court's factual inquiry was on an issue unrelated to the FLSA outside sales exemption-that is, on the efficacy in reducing health care costs of barring pharmaceutical companies and PSRs from using

particular data to target physicians, rather than on whether the activities in which PSRs engage constitute "sales." Therefore, both the use of the term "sales" in the factual section of the concurrence/dissent, and the majority's observation that PSRs' effort "works" in increasing their companies' market shares for a given product, are simply irrelevant to disposition of Defendant's motion. The factual record before this Court as to whether Schering's PSRs make "sales" is undisputed, and the *IMS Health* opinions do not address or advance the analysis of whether PSRs are engaged in or consummate "sales" as defined in 29 U.S.C. § 203(k) and 29 C.F.R. § 541.501(b).

Defendant also points to *Medtronic, Inc. v. Gibbons,* 527 F.Supp. 1085 (D.Minn.1981) for its description of the work that cardiac pacemaker manufacturers' "sales representatives" do in promoting their employers' products. *Medtronic* held that the plaintiff pacemaker manufacturer was entitled to a preliminary injunction preventing its former employee Gibbons from violating a restrictive covenant in an employment contract "by attempting to divert any business from Medtronic by soliciting, contacting, or communicating with any customers for the Medtronic's products." *Id.* at 1095. The *Medtronic* court explained that while Medtronic sold pacemakers ***401** to hospitals, hospitals opted to buy these products "on recommendations from a physician or other medical personnel treating a patient" to whom sales representatives promoted the pacemakers. *Id.* at 1094 n. 3. The court went on to explain that because "a contractual provision['s] ... language will be construed most strongly against the drafter" (here, Medtronic), *id.*, "[t]he term customers

shall be deemed to include hospitals, physicians, surgeons, or other hospital personnel directly involved in deciding which pacemaker to recommend for purchase," *id.* at 1095. While some courts have found *Medtronic* 's description of pacemaker sales instructive in applying the FLSA outside sales exemption,[15] the issue in *Medtronic* was unrelated to the FLSA outside sales exemption. Moreover, that court construed the term "customer" in line with the applicable rule of contract construction rather than the statutory and regulatory definitions of the term "sale" and narrow construction of the exemption mandated under the FLSA. This Court is therefore unpersuaded that *Medtronic* carries any relevance to the issue regarding the FLSA outside sales exemption.[16]

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[15] *See, e.g., In re Novartis,* 593 F.Supp.2d at 649-50; *see also Yacoubian* and *Delgado,* slip ops. at 8-9. The Court discusses below these two cases from the Central District of California.

[16] Defendant's reliance on *Guidant Sales Corp. v. George,* No. Civ. 01-1638(MJD/JGL), 2001 WL 1491317, 2001 U.S. Dist. LEXIS 25538 (D.Minn. Nov. 19, 2001) is unavailing for the same reasons as is *Medtronic.* The *Guidant Sales* court decided a question almost identical to that at issue in *Medtronic,* and granted a preliminary injunction to a cardiac rhythm management device company preventing George, its former employee, from "directly or indirectly selling, soliciting the sale of, supporting the sale or implantation or other use of, or otherwise having any involvement whatsoever with the sale, manufacturing, research and development, marketing or other business aspect of" products similar to the Guidant products he

Defendant's reliance on *Palmieri v. Nynex Long Distance Co.*, No. Civ. 04-138-PS, 2005 WL 767170, 2005 U.S. Dist. LEXIS 6057 (D.Me. Mar. 28, 2005), *aff'd*, 437 F.3d 111 (1st Cir.2006), is also unavailing. There, the First Circuit did not address that plaintiff's argument as to the federal outside sales exemption. *Palmieri*, 437 F.3d at 113 ("In this appeal, Palmieri contests only the district court's resolution of his claim for overtime pay under Maine law."). Moreover, at the district court Palmieri-a Corporate Account Manager expected to sell products and services on Verizon's high-speed voice and data networks to large customers, and to handle those customers' complaints, *see* 437 F.3d at 112-did not dispute that he made *some* sales, and instead argued that under an indicia-of-sales analysis making sales was not his primary duty. *See* 2005 WL 767170, *12-*15, 2005 U.S. Dist. LEXIS 6057, *42-*53. Because Schering's PSRs make or consummate no sales at all, the indicia-of-sales analysis is inapplicable, and therefore *Palmieri* is inapplicable.

Finally, Defendant also relies on seven cases from the Central District of California holding that PSRs fall within the outside salesperson exemption to California's state-law overtime laws. *Ruggeri I* and *Ruggeri II* provide lengthy explanations for this Court's rejection of four of these cases.[17] *See* ***402**

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once promoted. *Guidant Sales*, 2001 WL 1491317, *8, 2001 U.S. Dist. LEXIS 25538, *23.

[17] *See Brody v. AstraZeneca Pharmaceuticals, LP*, No. CV 06-06862 ABC (MANx), slip op. (C.D. Cal. June 11, 2008); *Menes v. Roche Labs., Inc.*, No. 2:07-cv-01444-ER-FFMx, 2008

Ruggeri I, 585 F.Supp.2d at 268-71; *Ruggeri II*, 585 F.Supp.2d at 312-17; *accord Smith*, 2008 WL 5427802, *6, 2008 U.S. Dist. LEXIS 104952, *16-*18; *Amendola v. Bristol-Myers Squibb Co.*, 558 F.Supp.2d 459, 470, 472 (S.D.N.Y.2008) (rejecting these cases because they "do not acknowledge that the FLSA's exemptions must be narrowly construed against employers, or address the governing principles of statutory construction in grappling with the plain meaning of the regulatory term 'sales.' "). The fifth case, *Rivera v. Schering Corp.*, No. CV 08-1743-GW(JCx), slip op. (C.D.Cal. Aug. 14, 2008),[18] is unavailing in light of the fact that its one-paragraph discussion of the outside salesperson exemption relies exclusively on these four cases, provides no independent analysis, and limits its holding to California law. *See Rivera* slip op. at 3-4 & 4 n. 3 ("Four different judges within this District have decided this question within the last year, and all have reached the conclusion that individuals in functionally the exact same employment as Plaintiff fit within the 'outside salespersons' exemption recognized by California's Labor Code and the relevant IWC Wage Order").

The final two cases, issued by the same court on

WL 612054, 2008 U.S. Dist. LEXIS 4230 (C.D.Cal. Jan. 7, 2008); *Barnick v. Wyeth*, 522 F.Supp.2d 1257 (C.D.Cal.2007); *D'Este v. Bayer Corp.*, No. CV 07-3206-JFW (PLAx), 2007 U.S. Dist. LEXIS 87229 (C.D.Cal. Oct. 9, 2007).

[18] *Rivera* is unavailable on either Westlaw or Lexis, but Defendant appended a copy to its motion. (Ex. A to Def.'s Not. Suppl. Auth. [Doc. # 109].)

the same day and containing verbatim the same analysis of the FLSA outside sales exemption, conclude that although "[r]egulations and ethics preclude physicians from ever making a binding commitment to a [PSR] to prescribe a certain drug," they "directly control which, and how much, of any medication is purchased by patients," so it is physicians-"the lynchpins" of "the drug-company-to-patient supply or distribution chain"-whose decisions drive the patient demand, which in turn drives a pharmaceutical company's sales to wholesalers, such that PSRs' dealings with physicians should be considered sales under the regulations. *Yacoubian v. Ortho-McNeil Pharmaceutical Corp.*, No. SACV 07-127-CJC (MLGx), slip op. at 5-11 (C. D.Cal. Feb. 6, 2009); *Delgado v. Ortho-McNeil Primary Care, Inc.*, No. SACV-07-263-CJC (MLGx), slip op. at 5-11 (C.D.Cal. Feb. 6, 2009).[19] This Court declines to follow *Yacoubian* and *Delgado* because of what it sees as their misplaced reliance on *IMS Health* and *In re Novartis* as well as *Jewel Tea Co.*'s generic description of the outside sales exemption and *Medtronic* 's construction of an employment contract.

It is the clarity of the statutory and regulatory language at issue defining the conduct and activity which constitutes "selling" or making a "sale" which undermines Schering's use of the term "sales" to classify PSRs' work as exempt from FLSA's overtime

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[19] *Yacoubian* and *Delgado* are unavailable on either Westlaw or Lexis, but Defendant appended copies to its motion. (Exs. A & B to Def.'s Not. Suppl. Auth. [Doc. # 128].)

pay provisions[20] and which renders unpersuasive other cases' characterizations of PSRs' work.[21] Because ***403** PSRs undisputedly do not "sell" or make any "sales" as those terms are defined in the FLSA and its implementing regulations, they fall outside the FLSA's outside sales exemption.

IV. Conclusion

For the reasons set forth above, Defendant's Motion for Summary Judgment [Doc. # 85] is DENIED.

IT IS SO ORDERED.

/s/

Janet Bond Arterton, U.S.D.J.

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[20] It is the FLSA statute and regulations, applied to the record before the Court, which determines that whether that PSRs fall outside the outside sales exemption. Therefore, Defendant's suggestion that the Court should find Plaintiffs exempt because "[p]harmaceutical companies across the country are facing an epidemic ... characterized by a rash of lawsuits that threatens the way the pharmaceutical industry has conducted business for decades" resulting from "an aggressive advertising campaign launched by Plaintiffs' counsel on the Internet to drum up plaintiffs" (Def.'s Mem. Supp. at 2-3) is irrelevant.

[21] To hold PSRs within the outside sales exemption on the basis of glosses on the effect of their promotional activities in marketing Schering's prescription pharmaceutical products would unduly expand the plain meaning of the terms "sell" and "sale" under the FLSA and its implementing regulations.

Dated at New Haven, Connecticut this 30th day of March, 2009.

604 F. Supp. 2d 385 (D. Conn. 2009).

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 09-0437-cv

August Term, 2009

(Argued: February 19, 2010 Decided: July 6, 2010)

Docket No. 09-0437-cv

In re NOVARTIS WAGE AND HOUR LITIGATION

Before: KEARSE and HALL, Circuit Judges, RAKOFF, District Judge.*

Appeal from a judgment of the United States District Court for the Southern District of New York, Paul A. Crotty, Judge, dismissing claims of pharmaceutical company sales representatives for overtime pay under the Fair Labor Standards Act of 1938, 29 U.S.C. § 201 et seq., and state law, finding that such representatives fell within exemptions for outside salesmen and for administrative employees exercising discretion and independent judgment. See 593 F.Supp.2d 637 (2009).

Vacated and remanded.

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* Honorable Jed S. Rakoff, of the United States District Court for the Southern District of New York, sitting by designation.

*143 Jeremy Heisler, New York, New York (David W. Sanford, Katherine M. Kimpel, Sanford, Wittels & Heisler, Washington, D.C., Steven Wittels, Andrew Melzer, Sanford, Wittels & Heisler, New York, NY, on the brief), for Plaintiffs-Appellants.

Richard H. Schnadig, Chicago, IL, (Vedder Price, Chicago, IL, Jonathan A. Wexler, Vedder Price, New York, NY, on the brief), for Defendant-Appellee.

Jennifer R. Marion, United States Department of Labor, Washington, D.C. (Carol A. De Deo, Deputy Solicitor for National Operations, William C. Lesser, Deputy Associate Solicitor, Paul L. Frieden, Counsel for Appellate Litigation, United States Department of Labor, Washington, D.C., on the brief), for Amicus Curiae Secretary of Labor in support of Plaintiffs-Appellants.

Outten & Golden, New York, NY, (Justin M. Swartz, Rachel Bien, Outten & Golden, New York, NY, Catherine K. Ruckelshaus, National Employment Law Project, New York, NY, George A. Hanson, Bradley T. Wilders, Stueve Siegel Hanson, Kansas City, MO, Rebecca M. Hamburg, National Employment Lawyers Association, San Francisco, CA, Richard J. (Rex) Burch, Bruckner Burch, Houston, TX, of counsel), filed a brief on behalf of Amicus Curiae National Employment Lawyers Association in support of Plaintiffs-Appellants.

Paul, Hastings, Janofsky & Walker, Washington, D.C. (Neal D. Mollen, Paul, Hastings, Janofsky & Walker, Washington, D.C., Robin S. Conrad, Shane B. Kawka, National Chamber Litigation Center, Washington, D.C., of counsel), filed a brief on behalf of Amicus Curiae Chamber of Commerce of the United States of America in support of Defendant-

Appellee.

KEARSE, Circuit Judge:

In these consolidated class actions, the plaintiffs, current or former pharmaceutical sales representatives employed by defendant Novartis Pharmaceuticals Corporation ("Novartis"), appeal from a judgment of the United States District Court for the Southern District of New York, Paul A. Crotty, Judge, denying their claims under the Fair Labor Standards Act of 1938 ("FLSA" or the "Act"), 29 U.S.C. § 201 et seq., and state law, for overtime pay with respect to time worked in excess of 40 hours per week. The district court granted Novartis's motion for summary judgment on the ground that plaintiffs are outside salesmen and/or administrative employees who are exempted from the FLSA's overtime pay requirements. On appeal, plaintiffs contend that the district court did not properly apply the exemption standards set out in regulations promulgated under the FLSA by the United States Secretary of Labor (the "Secretary"), see 29 C.F.R. §§ 541.200-541.204, 541.500-541.504. The Secretary, appearing ***144** as amicus curiae, endorses that contention. For the reasons that follow, we agree with plaintiffs and the Secretary; we thus vacate the judgment of the district court.

I. BACKGROUND

Novartis researches, manufactures, markets, and sells pharmaceuticals. The plaintiffs are some 2,500 persons who were employed by Novartis at various times between March 23, 2000, and April 7, 2007, as sales representatives ("Reps") in California or New

York, and who are parties to class actions in the United States District Courts for the Central District of California or the Southern District of New York, respectively, along with Reps employed by Novartis in other states during that period who have opted to join these actions. The actions were consolidated in the Southern District of New York by the Judicial Panel on Multidistrict Litigation for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407. Plaintiffs alleged principally that under the FLSA and state law, they were entitled to overtime pay at the rate of one and one-half times their normal compensation for time worked in excess of 40 hours per week. The following facts are not in dispute.

A. Novartis's Use of Pharmaceutical Sales Representatives

To market its pharmaceuticals, Novartis has a team of "brand" managers who, cognizant of limitations imposed by the United States Food and Drug Administration ("FDA") , devise descriptions of the essential features of each Novartis drug. Marketing managers assist in the production of written promotional materials. Novartis has regional managers who are involved in hiring, firing, and business planning decisions, including working on marketing strategy with the marketing team. Reporting to the regional managers are district managers who supervise the Reps.

Under federal regulations, Novartis is prohibited from selling its prescription drugs directly to patients. Instead, Novartis typically sells its products to wholesalers, which sell them to individual pharmacies. Physicians write prescriptions that permit patients to purchase those

products from pharmacies. Novartis employs some 6,000 Reps nationwide and assigns them to make what Novartis characterizes as "sales" calls on physicians.

Reps do not sell the Novartis products to physicians. Although Novartis advertises openings for Reps as sales positions, the Reps' duties do not include "the exchange of good[s] or services, contracting to sell any good or service, consigning for the sale of any good or service, or obtaining orders or contracts for the use of facilities." (Plaintiffs' Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment ¶ 107; Defendant Novartis Pharmaceuticals Corporation's Responses to Plaintiffs' Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment ¶ 107.) Rather, in visits typically lasting no longer than five minutes, the Reps provide physicians with information about the benefits of particular Novartis pharmaceuticals and encourage the physicians to prescribe those products. Reps give physicians reprints of clinical studies reporting findings about the Novartis products. Reps also inform doctors as to whether Novartis products are among those for which insurers will pay, resulting in little or no cost to patients. The Reps give the physicians samples of drugs; these samples are not sold, and no money is exchanged. Indeed, selling drug samples is a federal crime. See 21 U.S.C. §§ 353 (c)(1), 333 (b)(1)(B). The goal of the Reps is to get physicians to say ***145** they will prescribe Novartis products for their patients.

To enable the Reps to reach that goal, Novartis puts them through a training program for several weeks. The training is extensive, ranging from

instruction on the medical benefits of each Novartis drug--and the way in which Reps should present favorable scientific studies--to matters of technique as detailed as how they should hold their pens when showing Novartis's written material to physicians.

In the training program, a Rep is taught how to question physicians to determine why they may be hesitant about prescribing Novartis products and then to offer arguments to overcome their reluctance. Novartis instructs the Reps on four "social styles" that a given individual may have in interacting with others and teaches the Reps how to tailor their presentations to a physician's particular social style. Novartis has also hired consultants to observe its most successful Reps and incorporate their techniques into the training program.

Novartis sets the number of times per trimester a Rep must call on each physician and how often specific drugs should be promoted. For each product in each trimester, Novartis has a principal marketing message--its "core message"--developed by the Novartis brand managers, which Reps are instructed to convey to physicians on each call. Novartis gives the Reps written promotional materials developed by its brand and marketing managers, including posters, brochures, and laminated cards, to use on sales calls. The Reps do not play any part in formulating the core message or the written materials; nor do they play any part in devising Novartis's advertising. During training, Reps are required to engage in role-playing, using scripts to practice delivering the core message and parrying objections from physicians.

Although the Novartis training material encourages the Reps to tailor their pitches to an individual physician, they are not allowed to deviate from the core message. They are not allowed to use any written materials other than those provided by Novartis. One Rep testified that Reps were expected to act like "robots" because of the limitations on what they could say during sales calls. If a physician asks a Rep a medical question for which Novartis has not prepared an answer, the Rep is required to refer the doctor to Novartis's medical department.

The Reps report to their district managers by telephone at least every week or two, and sometimes report or confer daily. In addition, once or twice a month, the district managers accompany the Reps on their visits to physicians. During these ride-alongs, the managers observe the Reps' meetings and critique their performance. Reps receive negative reviews if they deliver the Novartis core message in a way that violates FDA-imposed limitations or Novartis policies.

As the Reps do not make sales, they are trained to end their meetings with physicians with a "closing" in which they may ask, "Doctor, will you prescribe this product for your patients who suffer from [the appropriate medical conditions]?" They may also ask, "Doctor, do I have your commitment to prescribe it [?]" One Novartis district manager described this type of colloquy as a "persuasive sale" but acknowledged that there was no way to know whether any physician actually followed through on such a commitment. One Rep stated that a physician might answer affirmatively just to get the Rep out the door.

As to physicians who refuse to entertain office visits from Reps, Novartis instructs the Reps to use other techniques to make contact, such as showing up at hospitals *146 early in the morning before medical rounds. Reps also organize meals and other programs for physicians where speakers promote Novartis products. For such programs, Novartis maintains a list of cooperating doctors, from which Reps must book speakers. Reps manage the budgets for these events, but do so within limits set by Novartis managers; Novartis sets a minimum number of such events that it expects each Rep to hold.

Novartis does not know how many prescriptions individual physicians write for its products. It subscribes to several services that provide it with information as to when prescriptions for Novartis products are filled at pharmacies that report such information to the services; this information identifies the prescribing physicians. Because the data are gathered from pharmacies, however, these reports represent only the number of prescriptions the reporting pharmacies filled, not all the prescriptions actually written. Further, because some 19,000 pharmacies do not report sales to these services, Novartis has data for only about 72% of all filled prescriptions. Novartis extrapolates from the reported sales in order to estimate the sales at non-reporting pharmacies, and it believes those estimates generate a fairly accurate picture of how many prescriptions are being filled at non-reporting pharmacies; however, the latter prescriptions cannot be traced to particular physicians.

Notwithstanding the absence of actual information as to the numbers of prescriptions for

Novartis drugs written by particular physicians, the Reps, whose base wages are at least $455 a week, receive up to a quarter of their compensation as bonuses based on their performance with physicians. Given the limits of its ability to monitor physicians' actual prescriptions, Novartis sets goals for the number of prescriptions it hopes to have filled in a particular territory, and it pays a Rep a bonus when the number of filled prescriptions attributable to physicians in the Rep's territory exceeds the goal Novartis has set. Some Novartis Reps earn more than $100,000 a year. In 2005, Novartis Reps' total compensation averaged $91,539.

The FLSA provides that many employees must be paid one and one-half times their regular rate of compensation for time worked in excess of 40 hours a week, see 29 U.S.C. § 207(a)(1), but provides that certain categories of workers are excluded from this requirement, see id. § 213. Novartis Reps are expected to be in the field from 8 a.m. to 5 p.m. on work days; they eat lunch with physicians or while driving to or from their physician visits; and they attend the mandatory dinner programs, which sometimes prevent them from returning home before 9 or 10 p.m. Notwithstanding a standard week of five such nine-hour days plus the occasional evening work, Novartis does not give its Reps overtime pay. As is the practice throughout the pharmaceuticals industry, Novartis treats its Reps as exempt from the overtime pay requirement in the FLSA, as well as from comparable state-law requirements.

B. The Decision of the District Court

In the consolidated proceedings, Novartis moved for summary judgment dismissing the complaints on

the ground that plaintiffs were "outside salesm[e]n" and/or "administrative" employees, 29 U.S.C. § 213(a)(1), and thus exempt from the overtime pay provisions of FLSA and state labor laws. Novartis also argued that those Reps who earned more than $100,000 a year were exempt under 29 C.F.R. § 541.601 (entitled "Highly compensated employees"). Plaintiffs cross-moved for partial summary judgment ruling *147 that they are not in an exempt category.

Ruling that it need not determine whether any Reps were exempt as highly compensated employees, the district court denied plaintiffs' motion and granted Novartis's motion on the ground that the "Reps are not entitled to overtime compensation because they are exempt from coverage as outside salespersons under the FLSA and state laws, and even if they are not outside salespersons, they are administrative employees and are still exempt." In re Novartis Wage & Hour Litigation, 593 F.Supp.2d 637, 640 (S.D.N.Y. 2009) ("Novartis I").

With respect to the contention that the Reps were exempt as outside sales employees, see 29 U.S.C. § 213(a)(1); 29 C.F.R. § 541.500, the district court reasoned that the Reps met the spirit and the letter of that exemption. It stated that excluding Reps from the exemption merely because they may not "'sell'" in a "technical[]" sense, Novartis I, 593 F.Supp.2d at 649 (citing Jewel Tea Co. v. Williams, 118 F.2d 202 (10th Cir. 1941)), would "ignore[] the Act's spirit, purpose, and goals." Novartis I, 593 F.Supp.2d at 648. The court stated that

> Jewel Tea teaches that outside salespersons are exempt from the overtime requirement not because they "sell," as that term is

> technically defined, but rather because they (1) generate commissions for themselves through their work and (2) work with minimal supervision, making adherence to an hours-based compensation scheme impractical.

Novartis I, 593 F.Supp.2d at 648-49 (emphasis added). The court also found that Reps do make sales for Novartis ("NPC"), stating as follows:

> Legally, Reps cannot sell NPC drugs directly to physicians. . . . Further, physicians have an ethical obligation to prescribe only drugs suitable for their patients' medical needs, meaning that they cannot make a binding commitment to a Rep to prescribe certain NPC products. . . . Nevertheless, . . . the physicians called upon by Reps ultimately control the purchase of NPC products by writing prescriptions. . . . [A]bsent a prescription from a doctor, the patient end-users of NPC drugs are not able to obtain those drugs. NPC spends in excess of $500 million annually to have its Reps meet on a frequent and repeat basis with these physicians to seek their commitments to prescribe NPC products. In other words, Reps make sales in the sense that sales are made in the pharmaceutical industry.

Id. at 650 (emphases added).

Rejecting plaintiffs' contention that the Reps do not make sales because sales of pharmaceuticals are made only by manufacturers to wholesale distributors, then by distributors to pharmacies, and

finally by pharmacies to patients, the district court stated that

> [t]he Court cannot ignore reality. Distributors are not the end-users of NPC's products. If physicians did not prescribe NPC products, patients would be unable to buy them and distributors would have no incentive to make purchases from NPC. The purchase cycle commences with a prescription from physicians, who are therefore the appropriate target of the Reps' sales efforts. When the physician writes a prescription for the NPC product, then a sale can take place.

Id.

With respect to the exemption for administrative employees, see 29 U.S.C. § 213(a)(1); 29 C.F.R. §§ 541.200, 541.202, the district court concluded that the Reps also fell within that category, stating that ***148** they earn in excess of $455 a week, "they engage in work that is directly related to the management or general business operations of NPC and they exercise discretion and independent judgment with respect to matters of significance." Novartis I, 593 F.Supp.2d at 655. The district court concluded that Reps are engaged in work related to the management or general business operations of Novartis because Reps are not engaged in the production of Novartis pharmaceuticals and because the Reps are critical to dissemination of information about Novartis products:

> Reps meet with physicians and provide them with information about NPC drugs in an attempt to persuade the physicians to write

> prescriptions for those drugs. The Reps' success in obtaining prescriptions is critical to NPC's business. The sizeable incentive payments made to Reps for generating prescriptions, as well as the more than $500 million paid to the 6,000 Reps, buttress[] the conclusion that obtaining prescriptions for its drugs is critical to NPC's success. There is no other rational explanation for the commitment of this level of financial resources to NPC's sales effort.

Id. at 656. The court concluded that Reps exercise "discretion and independent judgment with respect to matters of significance" because

> Reps are expected to use initiative to increase the number of prescriptions written for their drugs--oftentimes, this involves building a good rapport with the physicians and their staffs. Within the confines of the "core messages" created by NPC, Reps must decide how best to present their information and must determine what type of "close" is most appropriate in a given situation. This, of course, depends on how much time the physician will allow the Rep, the physician's patient base and prescribing history, and numerous other factors. Reps set their daily call schedules and are expected to use their entertainment budgets to host informational events for the physicians on their target lists. In carrying out these activities, they are quite clearly attempting to increase prescriptions for their drugs--a matter of considerable significance for NPC.

Id. at 657. The district court was unpersuaded that Novartis's training and expectations rendered Reps "robots" or automatons who did not exercise significant discretion:

> These labels are not facts, but merely arguments designed to avoid the overtime exemptions. They do not begin to answer why or how a robot or an automaton could or should earn an average salary of $91,500 per year. Nor do they explain why NPC would employ 6,000 Reps at a cost in excess of half a billion dollars per year. They are an attempt to avoid the consequences of what Reps do every day--arranging to call on physicians and, after assessing how much time is available for the call, choosing the best possible approach to convince the physician to prescribe NPC drugs the next time an appropriate patient opportunity presents itself. NPC pays a good salary and material incentives to encourage this behavior. Reps are given drug samples, printed materials, and core messages. They are dispatched to the offices of physicians in an attempt to convince those physicians to prescribe NPC products. It defies logic to accept that, in such a situation, Reps are expected to do nothing but chant slogans and mouth platitudes. At the bare minimum, Reps must be capable of tailoring their presentation to a given timeframe--deciding how best to convey the "core message" in a manner that will have the desired effect on the physician. ***149** Such a decision involves making an independent judgment, free of

> direct oversight, even if NPC has provided Reps with guidelines for conveying certain information in a certain manner. Thus, while the exact nature of the discretion and independent judgment exercised by Reps may be in dispute, . . . on the present facts, NPC's Reps have discretion and exercise independent judgment.

Id.

Accordingly, having found both the outside salesman and administrative employee exemptions applicable, the district court granted Novartis's motion for summary judgment dismissing plaintiffs' claims under the FLSA. In addition, finding that the New York overtime pay exemptions were defined and applied in the same manner as those in the FLSA, see Novartis I, 593 F.Supp.2d at 646, and that California law, although differing slightly in the ways it defined the exemption, was "essentially the same as the FLSA and New York law," id. at 647, the court granted summary judgment dismissing plaintiffs' state-law claims.

This appeal followed.

II. DISCUSSION

On appeal, the Reps contend principally that the district court erred in concluding that they are outside sales employees, given that the "[t]he undisputed evidence in this case shows that the Reps do not obtain orders, form contracts, or engage in any type of sale as that term is defined by the FLSA" (Plaintiffs' brief on appeal at 46), and in concluding that Reps are administrative employees given that "[t]hey lack discretion and independent judgment

within [the] meaning of the administrative exemption" (id. at 63). Novartis defends the district court's conclusions, arguing that Reps make sales "in the only practical sense applicable to the pharmaceuticals industry" (Novartis brief on appeal at 27), and that, in so doing, the Reps exercise discretion and independent judgment (see id. at 48-55).

The Secretary of Labor, participating in this appeal as an amicus curiae in support of the Reps, points out that Department of Labor ("DOL" or "Department") regulations promulgated under the FLSA (a) provide, in pertinent part, that an "outside salesman" is one who, inter alia, has the primary duty of "making sales," and (b) provide that an exempt "administrative" employee is one who, inter alia, exercises discretion and independent judgment with respect to matters of significance. The Secretary contends that because the Reps do not make sales or obtain orders and do not exercise discretion and independent judgment, they are not within the "outside salesman" or the "administrative" employee categories that are exempted from the FLSA overtime pay requirements. Novartis argues that the Secretary's interpretations are contrary to the regulations themselves. The United States Chamber of Commerce has filed a brief as amicus curiae in support of Novartis, citing Gonzales v. Oregon, 546 U.S. 243, 257 (2006), and arguing that the Secretary's interpretations are not entitled to deference, on the theory that the regulations merely parrot the FLSA's language and that the Secretary is thus interpreting only the words of Congress, not those of the regulations.

For the reasons that follow, we conclude that the Secretary's regulations define and delimit the terms used in the statute; that under those regulations as interpreted by the Secretary, the Reps are not outside salesmen or administrative employees; and that the Secretary's interpretations are entitled to "controlling" deference, Auer v. Robbins, 519 U.S. 452, 461 (1997).

*150 A. The FLSA's Overtime Pay Requirement

Congress enacted the FLSA in 1938 to combat "labor conditions detrimental to the maintenance of the minimum standard of living necessary for health, efficiency, and general well-being of workers." FLSA § 2 (a), 29 U.S.C. § 202 (a). Section 7(a)(1) of the FLSA provides, in pertinent part, that

> no employer shall employ any of his employees who in any workweek ... is employed in an enterprise engaged in commerce or in the production of goods for commerce, for a workweek longer than forty hours unless such emplovee receives compensation for his employment in excess of the hours above specified at a rate not less than one and one-half times the regular rate at which he is employed.

29 U.S.C. § 207(a)(1) (emphases added). To the extent pertinent to this appeal, FLSA § 13(a)(1) exempts from that overtime pay requirement

> any employee employed in a bona fide ... administrative ... capacity ... or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary[)].

29 U.S.C. § 213(a)(1) (emphases added). The FLSA definitions section provides that

> "[s]ale" or "sell" includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition.

FLSA § 3(k), 29 U.S.C. § 203(k).

"The overtime requirements of the FLSA were meant to apply financial pressure to 'spread employment to avoid the extra wage' and to assure workers 'additional pay to compensate them for the burden of a workweek beyond the hours fixed in the act.'" Davis v. J.P. Morgan Chase & Co., 587 F.3d 529, 535 (2d Cir. 2009) (quoting Overnight Motor Transportation Co. v. Missel, 316 U.S. 572, 578 (1942), superseded by statute, Portal-to-Portal Pay Act of 1947, ch. 52, 61 Stat. 84). Because the FLSA is a "remedial law," Reiseck v. Universal Communications of Miami, Inc., 591 F.3d 101, 104 (2d Cir. 2010), exemptions to the overtime pay requirement are "'narrowly construed against the employers seeking to assert them and their application limited to those establishments plainly and unmistakably within their terms and spirit.'" Bilyou v. Dutchess Beer Distributors, Inc., 300 F. 3d 217, 222 (2d Cir. 2002) (quoting Arnold v. Ben Kanowsky, Inc., 361 U.S. 388, 392 (1960)). The burden of proving that employees fall within such an exemption is on the employer. See, e.g., Bilyou v. Dutchess Beer Distributors, Inc., 300 F.3d at 222.

We review de novo a district court's grant or denial of summary judgment, viewing the record in the light most favorable to the party against whom summary judgment is sought. See, e.g., Dillon v. Morano, 497 F.3d 247, 251 (2d Cir. 2007). Whether

the duties of a job qualify an employee for a FLSA exemption is a question of law, which we review de novo. See, e.g., Icicle Seafoods, Inc. v. Worthington, 475 U.S. 709, 714 (1986); Zheng v. Liberty Apparel Co., 355 F.3d 61, 76 (2d Cir. 2003).

B. The "Outside Salesman" Exemption

Pursuant to her statutory mandate to "define[] and delimit[]" the terms "outside salesman" and "administrative" employee, 29 U.S.C. § 213(a)(1), the Secretary has promulgated several regulations. Regulations issued in 2004 provide, inter alia, that "[a] job title alone is insufficient *151 to establish the exempt status of an employee," 29 C.F.R. § 541.2; rather, that status may be determined only on the basis of the employee's "salary and duties," id. With respect to "outside salesman," the regulations provide as follows:

> (a) The term "employee employed in the capacity of outside salesman" in section 13(a)(1) of the Act shall mean any employee:
>
> (1) Whose primary duty is:
>
> (i) making sales within the meaning of section 3(k) of the Act, or
>
> (ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer; and
>
> (2) Who is customarily and regularly engaged away from the employer's place or places of business in performing such primary duty.
>
> (b). . . . In determining the primary duty of an outside sales employee, work performed

> incidental to and in conjunction with the employee's own outside sales or solicitations, including incidental deliveries and collections, shall be regarded as exempt outside sales work. Other work that furthers the employee's sales efforts also shall be regarded as exempt work including, for example, writing sales reports, updating or revising the employee's sales or display catalogue, planning itineraries and attending sales conferences.

Id. § 541.500 (emphases added). Elaborating on the meaning of sales of commodities, as contrasted with sales of services or the use of facilities, the regulations provide that

> [s]ales within the meaning of section 3(k) of the Act include the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property. Section 3 (k) of the Act states that "sale" or "sell" includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition.

29 C.F.R. § 541.501 (b) (emphasis added).

The regulations go on to describe the circumstances in which an employee's efforts to "promot[e]" a product constitute--or do not constitute—"sales" within the meaning of the regulations:

> (a) Promotion work is one type of activity often performed by persons who make sales, which may or may not be exempt outside sales work, depending upon the

> circumstances under which it is performed. Promotional work that is actually performed incidental to and in conjunction with an employee's own outside sales or solicitations is exempt work. On the other hand, promotional work that is incidental to sales made, or to be made, by someone else is not exempt outside sales work. . . .
>
> (b) A manufacturer's representative, for example, may perform various types of promotional activities such as putting up displays and posters, removing damaged or spoiled stock from the merchant's shelves or rearranging the merchandise. Such an employee can be considered an exempt outside sales employee if the employee's primary duty is making sales or contracts. Promotional activities directed toward consummation of the employee's own sales are exempt. Promotional activities designed to stimulate sales that will be made by someone else are not exempt outside sales work.

Id. §§ 541.503 (a)-(b) (emphases added).

As described in the preamble to the 2004 DOL regulations, these rules had their origins in regulations adopted after DOL hearings conducted in the 1940s (resulting in a 1940 "Stein Report" and a 1949 *152 "Weiss Report"), see Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22122, 22124 (Apr. 23, 2004) ("2004 Final Rule" or "Final Rule"). The Final Rule's preamble ("Preamble") discussed

whether an outside employee's promotional activities qualify him as a "salesman" and emphasized that no one could be considered a salesman within these regulations unless he in some sense made a sale.

Addressing concerns expressed by such groups as the Grocery Manufacturers Association, the National Association of Manufacturers, and the U.S. Chamber of Commerce for the emphasis on an employee's "own" sales, given the technological advances that enable a customer to place its own order directly with a supplier, the DOL agreed that a determination of whether an employee is exempt as an outside salesman "should not depend on whether it is the sales employee or the customer who types the order into a computer system and hits the return button." 2004 Final Rule at 22163. But while the Preamble stated that the DOL "agree[d] that technological changes in how orders are taken and processed should not preclude the [outside salesman] exemption for employees who in some sense make the sales," id. at 22162, it emphasized that

> the Department does not intend to change any of the essential elements required for the outside sales exemption, including the requirement that the outside sales employee's primary duty must be to make sales or to obtain orders or contracts for services. An employer cannot meet this requirement unless it demonstrates objectively that the employee, in some sense, has made sales. See 1940 Stein Report at 46 (outside sales exemption does not apply to an employee "who does not in some sense make a sale") (emphasis added). Extending the outside sales exemption to include all

> promotion work, whether or not connected to an employee's own sales, would contradict this primary duty test.

2004 Final Rule at 22162 (first two emphases ours). The Preamble also elaborated on the primary-duty standard:

> Employees have a primary duty of making sales if they "obtain a commitment to buy" from the customer and are credited with the sale. See 1949 Weiss Report at 83 ("In borderline cases the test is whether the person is actually engaged in activities directed toward the consummation of his own sales, at least to the extent of obtaining a commitment to buy from the person to whom he is selling. If his efforts are directed toward stimulating the sales of his company generally rather than the consummation of his own specific sales his activities are not exempt").

2004 Final Rule at 22162-22163 (emphases ours).

We note that the distinction between obtaining commitments to buy and promoting sales by other persons has been respected in areas other than the pharmaceutical industry. See, e.g., Gregory v. First Title of America, Inc., 555 F.3d 1300, 1309 (11th Cir. 2009) (employee who obtained commitments to buy her employer's title insurance service and was credited with those sales, and all of whose efforts were directed towards the consummation of her own sales and not towards stimulating sales for the employer in general, was an outside sales employee within the meaning of the FLSA and the regulations); Clements v. Serco, Inc., 530 F.3d 1224,

1228 (10th Cir. 2008) (civilian military recruiters who did not obtain commitments from recruits were not outside salesmen within the meaning of, e.g., *153 29 C.F.R. § 541.504); Wirtz v. Keystone Readers Service, Inc., 418 F.2d 249, 253, 260 (5th Cir. 1969) ("student salesmen" were not outside sales employees where their promotional activities were incidental to sales made by others).

We think it clear that the above regulations, defining the term "sale" as involving a transfer of title, and defining and delimiting the term "outside salesman" in connection with an employee's efforts to promote the employer's products, do far more than merely parrot the language of the FLSA. The Secretary's interpretations of her regulations are thus entitled to "controlling" deference unless those interpretations are "'plainly erroneous or inconsistent with the regulation.'" Auer, 519 U.S. at 461 (quoting Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 359 (1989) (other internal quotation marks omitted)).

We find no such inconsistency and see no such error. Although Novartis contends that the position taken by the Secretary as amicus on this appeal is contrary to the regulations, we disagree. The basic premise of the regulations explaining who may properly be considered an exempt "outside salesman" --a term for which the FLSA explicitly relies on the Secretary to promulgate defining and delimiting regulations--is that an employee is not an outside salesman unless he does "in some sense make the sales," 2004 Final Rule at 22162. And although that phrase (on which Novartis relies heavily (see, e.g., Novartis brief on appeal at 12, 22, 25, 29)) does not appear in any of the regulations that explicate the

term "outside salesman," the regulations quoted above make it clear that a person who merely promotes a product that will be sold by another person does not, in any sense intended by the regulations, make the sale. The position taken by the Secretary on this appeal is that when an employee promotes to a physician a pharmaceutical that may thereafter be purchased by a patient from a pharmacy if the physician--who cannot lawfully give a binding commitment to do so--prescribes it, the employee does not in any sense make the sale. Thus, the interpretation of the regulations given by the Secretary in her position as amicus on this appeal is entirely consistent with the regulations.

Nor can we conclude that the regulations constitute an erroneous interpretation of the FLSA definition of "sale" to "include[] any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition," 29 U.S.C. § 203(k). Although the phrase "other disposition" is a catch-all that could have an expansive connotation, we see no error in the regulations' requirement that any such "other disposition" be "in some sense a sale." Such an ejusdem generis-type interpretation is consistent with the interpretive canon that exemptions to remedial statutes such as the FLSA are to be read narrowly, see Arnold, 361 U.S. at 392; see generally A.H. Phillips, Inc. v. Walling, 324 U.S. 490, 493 (1945), and is neither erroneous nor unreasonable, see, e.g., Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43 (1984) We accordingly owe the Secretary's interpretation deference, and we turn to the question of its applicability to the present cases.

There is no genuine dispute over the sales path generally traversed by Novartis pharmaceuticals. As described in Part I.A. above, Novartis sells its drugs to wholesalers; the wholesalers then sell them to pharmacies; and the pharmacies ultimately sell the drugs to patients who *154 have prescriptions for them. The Reps promote the drugs to the physicians; the Reps do not speak to the wholesalers or to the pharmacies or to the patients.

Nor is there any dispute as to what occurs during the Reps' "sales" calls on physicians. The meetings are brief--generally less than five minutes--and the physicians neither buy pharmaceuticals from the Reps nor commit to buying anything from the Reps or from Novartis. The Reps may give physicians free samples, but the Reps cannot transfer ownership of any quantity of the drug in exchange for anything of value. The physician is of course an essential step in the path that leads to the ultimate sale of a Novartis product to an end user; a patient cannot purchase the product from a pharmacy without a prescription, and it is the physician who must be persuaded that a particular Novartis drug may appropriately be prescribed for a particular patient. But it is reasonable to view what occurs between the physicians and the Reps as less than a "sale."

Novartis suggests that "sale" should be read broadly in light of the statement in the Preamble that "'[e]mployees have a primary duty of making sales if they "obtain a commitment to buy" from the customer and are credited with the sale.'" (Novartis brief on appeal at 23 (quoting 2004 Final Rule at 22162) (emphases in brief).) It argues that the Reps "make sales in some sense" because "they are responsible for eliciting commitments from the

physicians on whom they call to write prescriptions for NPC drugs and that these prescriptions are, in essence, orders for NPC drugs to be used by the patients in purchasing the drugs from pharmacies." (Novartis brief on appeal at 25-26 (emphasis in original) (internal quotation marks omitted).) Novartis's emphatic reliance on the word "commitments," however, does not lead to a conclusion that the Reps make sales, for it ignores the nature of the "commitment" expressly envisioned by the Secretary in enacting the regulations: "a commitment to buy," 2004 Final Rule at 22162, 22163 (emphasis added). The type of "commitment" the Reps seek and sometimes receive from physicians is not a commitment "to buy" and is not even a binding commitment to prescribe. As the district court noted, "physicians have an ethical obligation to prescribe only drugs suitable for their patients' medical needs, meaning that they cannot make a binding commitment to a Rep to prescribe" a particular Novartis product. Novartis I, 593 F.Supp.2d at 650 (emphasis added). Thus, although physicians may say that they will prescribe a given Novartis drug for patients with appropriate diagnoses, such an assurance is not a binding commitment, and physicians remain entirely free to prescribe a competing product made by a company other than Novartis.

In sum, where the employee promotes a pharmaceutical product to a physician but can transfer to the physician nothing more than free samples and cannot lawfully transfer ownership of any quantity of the drug in exchange for anything of value, cannot lawfully take an order for its purchase, and cannot lawfully even obtain from the physician a

binding commitment to prescribe it, we conclude that it is not plainly erroneous to conclude that the employee has not in any sense, within the meaning of the statute or the regulations, made a sale.

Novartis points out that a number of district courts have held that pharmaceutical sales representatives are exempt from the FLSA overtime pay requirements as outside salesmen (and/or administrative employees). Those cases are, of course, not binding on us, and their reasoning does not persuade us that the Secretary's ***155** interpretations of the regulations should be disregarded. To the extent that the pharmaceuticals industry wishes to have the concept of "sales" expanded to include the promotional activities at issue here, it should direct its efforts to Congress, not the courts. Given the existing statute and regulations, we conclude that the district court should have ruled that the Reps are not outside salesmen within the meaning of the FLSA and the regulations.

C. The "Administrative" Employee Exemption

The Secretary's regulations interpreting the FLSA exemption for "any employee employed in a bona fide . . . administrative . . . capacity," 29 U.S.C. § 213(a)(1), establish three criteria that must be met for an employee to fit within that category. To be such an "administrative" employee, (1) the employee must earn at least $455 a week, (2) his "primary duty" must be "the performance of office or non-manual work directly related to the management or general business operations of the employer or the employer's customers," and (3) his "primary duty" must "include[] the exercise of discretion and

independent judgment with respect to matters of significance," 29 C.F.R. § 541.200(a); see, e.g., id. § 541.201 (elaborating on the second criterion); id. § 541.202 (elaborating on the third criterion). For purposes of this appeal, the relevant issue is whether Novartis has adduced sufficient evidence to permit a rational juror to infer that the Reps meet the third criterion.

With respect to the requirement that the employee's primary duty include "the exercise of discretion and independent judgment with respect to matters of significance," the regulations provide, in relevant part, as follows:

> In general, the exercise of discretion and independent judgment involves the comparison and the evaluation of possible courses of conduct, and acting or making a decision after the various possibilities have been considered. The term "matters of significance" refers to the level of importance or consequence of the work performed.
>
> (b) The phrase "discretion and independent judgment" must be applied in the light of all the facts involved in the particular employment situation in which the question arises. Factors to consider when determining whether an employee exercises discretion and independent judgment with respect to matters of significance include, but are not limited to: whether the employee has authority to formulate, affect, interpret, or implement management policies or operating practices; whether the employee carries out major assignments in conducting the

> operations of the business; whether the employee performs work that affects business operations to a substantial degree, even if the employee's assignments are related to operation of a particular segment of the business; whether the employee has authority to commit the employer in matters that have significant financial impact; whether the employee has authority to waive or deviate from established policies and procedures without prior approval; whether the employee has authority to negotiate and bind the company on significant matters; whether the employee provides consultation or expert advice to management; whether the employee is involved in planning long- or short-term business objectives; whether the employee investigates and resolves matters of significance on behalf of management; and whether the employee represents the company in handling complaints, arbitrating disputes or resolving grievances.
>
> ***156** . . . .
>
> (e) The exercise of discretion and independent judgment must be more than the use of skill in applying well-established techniques, procedures or specific standards described in manuals or other sources. . . .

Id. § 541.202(a), (b), and (e).

On appeal, the Reps contend that they do "low-level, discretionless marketing work, strictly controlled by Novartis," and that their duties and authority do not satisfy the requirements for applicability of the administrative employee

exemption. (Plaintiffs' brief on appeal at 40.) Novartis, in contending that the Reps exercise discretion and independent judgment, argues that the Reps, for example, "must determine how best to develop a rapport with a physician and develop strategies to engage physicians in an interactive dialogue to draw out their patient concerns, treatment styles and predilections"; must "be able to react to expressed physician concerns by emphasizing particular clinical findings regarding the efficacy and safety of NPC's drugs for specific patient types"; "must determine when and how to deliver the [Novartis-determined core] message, taking into consideration," e.g., "the prior call history with each physician, the physician's time constraints, expressed concerns, prescription-writing tendencies and patient population"; and must "determine how best to close each call by evaluating whether sufficient groundwork has been laid to seek the physician's commitment on that call to write prescriptions." (Novartis brief on appeal at 50-51.)

The Secretary points out that the regulations make clear that the requirement for authority to "exercise . . . discretion and independent judgment" means more than simply the need to use skill in applying well-established techniques or procedures prescribed by the employer, see 29 C.F.R. § 541.202 (e). The Secretary takes the position that for the administrative exemption to apply to the Reps, the regulations require a showing of a greater degree of discretion, and more authority to use independent judgment in matters of significance, than Novartis allows the Reps. Again we find it appropriate to defer to the Secretary's interpretation.

Comparing the record as to the Reps' primary duties against the illustrative factors set out in § 541.202 (b), for example, we see no evidence in the record that the Reps have any authority to formulate, affect, interpret, or implement Novartis's management policies or its operating practices, or that they are involved in planning Novartis's long-term or short-term business objectives, or that they carry out major assignments in conducting the operations of Novartis's business, or that they have any authority to commit Novartis in matters that have significant financial impact. Although Novartis argues that the Reps do commit Novartis financially when they enter into contracts with hotels, restaurants, and other venues for promotional events, "which may cost NPC thousands of dollars" (Novartis brief on appeal at 3-4), the record reveals that the Reps have been given budgets for such events by the Novartis managers and that the Reps have no discretion to exceed those budgets. Nor have we been pointed to any evidence that the Reps have authority to negotiate and bind Novartis on any significant matters, or have authority to waive or deviate from Novartis's established policies and procedures without its prior approval. What Novartis characterizes as the Reps' exercise of discretion and independent judgment--ability to answer questions about the product, ability to develop a rapport with a physician who has a certain social style, ability to remember past conversations with a given physician, ability to recognize ***157** when a message has been persuasive--are skills gained and/or honed in their Novartis training sessions. As described in Part I.A. above, these skills are exercised within severe limits imposed by Novartis. Thus, it is undisputed that the Reps, inter alia,

- have no role in planning Novartis's marketing strategy;
- have no role in formulating the "core messages" they deliver to physicians;
- are required to visit a given physician a certain number of times per trimester as established by Novartis;
- are required to promote a given drug a certain number of times per trimester as established by Novartis;
- are required to hold at least the number of promotional events ordered by Novartis;
- are not allowed to deviate from the promotional "core messages";
- and are forbidden to answer any question for which they have not been scripted.

Novartis argues that the Reps exercise a great deal of discretion because they are free to decide in what order to visit physicians' offices, free to decide how best to gain access to those offices, free to decide how to allocate their Novartis budgets for promotional events, and free to determine how to allocate their samples. (See Novartis brief on appeal at 51.) In light of the above controls to which Novartis subjects the Reps, we agree with the Secretary that the four freedoms advanced by Novartis do not show that the Reps are sufficiently allowed to exercise either discretion or independent judgment in the performance of their primary duties. Accordingly, we conclude that the district court should have ruled that the Reps are not bona fide administrative employees within the meaning of the FLSA and the regulations.

D. State Law

The district court concluded that the overtime wage requirements of New York law and California law are not meaningfully different from the requirements of the FLSA, see Novartis I, 593 F. Supp. 2d at 654, 658, and no party has argued on this appeal that the requirements differ. Accordingly, we also vacate the district court's rulings that the Reps fall within the exemptions provided by state law.

CONCLUSION

We have considered all of Novartis's arguments in support of the judgment and have found in them no merit. We vacate the judgment of the district court and remand for further proceedings not inconsistent with this opinion.

611 F.3d 141 (2d Cir. 2010).

APPENDIX D
29 U.S.C. § 202

§202. Congressional finding and declaration of policy

(a) The Congress finds that the existence, in industries engaged in commerce or in the production of goods for commerce, of labor conditions detrimental to the maintenance of the minimum standard of living necessary for health, efficiency, and general well-being of workers (1) causes commerce and the channels and instrumentalities of commerce to be used to spread and perpetuate such labor conditions among the workers of the several States; (2) burdens commerce and the free flow of goods in commerce; (3) constitutes an unfair method of competition in commerce; (4) leads to labor disputes burdening and obstructing commerce and the free flow of goods in commerce; and (5) interferes with the orderly and fair marketing of goods in commerce. That Congress further finds that the employment of persons in domestic service in households affects commerce.

(b) It is declared to be the policy of this chapter, through the exercise by Congress of its power to regulate commerce among the several States and with foreign nations, to correct and as rapidly as practicable to eliminate the conditions above referred to in such industries without substantially curtailing employment or earning power.

APPENDIX E
29 U.S.C. §203

§ 203. Definitions

As used in this chapter—

* * * *

(k) "Sale" or "sell" includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition.

* * * *

APPENDIX F
29 U.S.C. § 207

§ 207. Maximum hours

(a) Employees engaged in interstate commerce; additional applicability to employees pursuant to subsequent amendatory provisions

(1) Except as otherwise provided in this section, no employer shall employ any of his employees who in any workweek is engaged in commerce or in the production of goods for commerce, or is employed in an enterprise engaged in commerce or in the production of goods for commerce, for a workweek longer than forty hours unless such employee receives compensation for his employment in excess of the hours above specified at a rate not less than one and one-half times the regular rate at which he is employed.

(2) No employer shall employ any of his employees who in any workweek is engaged in commerce or in the production of goods for commerce, or is employed in an enterprise engaged in commerce or in the production of goods for commerce, and who in such workweek is brought within the purview of this subsection by the amendments made to this chapter by the Fair Labor Standards Amendments of 1966—

(A) for a workweek longer than forty-four hours during the first year from the effective date of the Fair Labor Standards Amendments of 1966,

(B) for a workweek longer than forty-two hours during the second year from such date, or

(C) for a workweek longer than forty hours after the expiration of the second year from such date, unless such employee receives compensation for his employment in excess of the hours above specified at a rate not less than one and one-half times the regular rate at which he is employed.

* * * *

APPENDIX G
29 U.S.C. § 213

§ 213. Exemptions

(a) Minimum wage and maximum hour requirements

The provisions of sections 206 (except subsection (d) in the case of paragraph (1) of this subsection) and 207 of this title shall not apply with respect to—

(1) any employee employed in a bona fide executive, administrative, or professional capacity (including any employee employed in the capacity of academic administrative personnel or teacher in elementary or secondary schools), or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary, subject to the provisions of subchapter II of chapter 5 of title 5, except that an employee of a retail or service establishment shall not be excluded from the definition of employee employed in a bona fide executive or administrative capacity because of the number of hours in his workweek which he devotes to activities not directly or closely related to the performance of executive or administrative activities, if less than 40 per centum of his hours worked in the workweek are devoted to such activities); or

(2) Repealed. Pub. L. 101–157, § 3(c)(1), Nov. 17, 1989, 103 Stat. 939.

* * * *

APPENDIX H
29 C.F.R. § 541.500

§ 541.500 General rule for outside sales employees.

(a) The term "employee employed in the capacity of outside salesman" in section 13(a)(1) of the Act shall mean any employee:

(1) Whose primary duty is:

(i) making sales within the meaning of section 3(k) of the Act, or

(ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer; and

(2) Who is customarily and regularly engaged away from the employer's place or places of business in performing such primary duty.

(b) The term "primary duty" is defined at § 541.700. In determining the primary duty of an outside sales employee, work performed incidental to and in conjunction with the employee's own outside sales or solicitations, including incidental deliveries and collections, shall be regarded as exempt outside sales work. Other work that furthers the employee's sales efforts also shall be regarded as exempt work including, for example, writing sales reports, updating or revising the employee's sales or display catalogue, planning itineraries and attending sales conferences.

(c) The requirements of subpart G (salary requirements) of this part do not apply to the outside sales employees described in this section.

APPENDIX I
29 C.F.R. § 541.501

§ 541.501 Making sales or obtaining orders.

(a) Section 541.500 requires that the employee be engaged in:

(1) Making sales within the meaning of section 3(k) of the Act, or

(2) Obtaining orders or contracts for services or for the use of facilities.

(b) Sales within the meaning of section 3(k) of the Act include the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property. Section 3(k) of the Act states that "sale" or "sell" includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition.

(c) Exempt outside sales work includes not only the sales of commodities, but also "obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer." Obtaining orders for "the use of facilities" includes the selling of time on radio or television, the solicitation of advertising for newspapers and other periodicals, and the solicitation of freight for railroads and other transportation agencies.

(d) The word "services" extends the outside sales exemption to employees who sell or take orders for a service, which may be performed for the customer by someone other than the person taking the order.

APPENDIX J
29 C.F.R. § 541.502

§ 541.502 Away from employer's place of business.

An outside sales employee must be customarily and regularly engaged "away from the employer's place or places of business." The outside sales employee is an employee who makes sales at the customer's place of business or, if selling door-to-door, at the customer's home. Outside sales does not include sales made by mail, telephone or the Internet unless such contact is used merely as an adjunct to personal calls. Thus, any fixed site, whether home or office, used by a salesperson as a headquarters or for telephonic solicitation of sales is considered one of the employer's places of business, even though the employer is not in any formal sense the owner or tenant of the property. However, an outside sales employee does not lose the exemption by displaying samples in hotel sample rooms during trips from city to city; these sample rooms should not be considered as the employer's places of business. Similarly, an outside sales employee does not lose the exemption by displaying the employer's products at a trade show. If selling actually occurs, rather than just sales promotion, trade shows of short duration (*i.e.*, one or two weeks) should not be considered as the employer's place of business.

APPENDIX K
29 C.F.R. § 541.503

§ 541.503 Promotion work.

(a) Promotion work is one type of activity often performed by persons who make sales, which may or may not be exempt outside sales work, depending upon the circumstances under which it is performed. Promotional work that is actually performed incidental to and in conjunction with an employee's own outside sales or solicitations is exempt work. On the other hand, promotional work that is incidental to sales made, or to be made, by someone else is not exempt outside sales work. An employee who does not satisfy the requirements of this subpart may still qualify as an exempt employee under other subparts of this rule.

(b) A manufacturer's representative, for example, may perform various types of promotional activities such as putting up displays and posters, removing damaged or spoiled stock from the merchant's shelves or rearranging the merchandise. Such an employee can be considered an exempt outside sales employee if the employee's primary duty is making sales or contracts. Promotion activities directed toward consummation of the employee's own sales are exempt. Promotional activities designed to stimulate sales that will be made by someone else are not exempt outside sales work.

(c) Another example is a company representative who visits chain stores, arranges the merchandise on shelves, replenishes stock by replacing old with new merchandise, sets up displays and consults with the store manager when inventory runs low, but does not

obtain a commitment for additional purchases. The arrangement of merchandise on the shelves or the replenishing of stock is not exempt work unless it is incidental to and in conjunction with the employee's own outside sales. Because the employee in this instance does not consummate the sale nor direct efforts toward the consummation of a sale, the work is not exempt outside sales work.

APPENDIX L
69 Fed. Reg. 22122

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 541

RIN 1215-AA14

Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: This document provides the text of final regulations under the Fair Labor Standards Act implementing the exemption from minimum wage and overtime pay for executive, administrative, professional, outside sales and computer employees. These exemptions are often referred to as the "white collar" exemptions. To be considered exempt, employees must meet certain minimum tests related to their primary job duties and, in most cases, must be paid on a salary basis at not less than minimum amounts as specified in pertinent sections of these regulations.

EFFECTIVE DATE: These rules are effective on August 23, 2004.

* * * *

SUPPLEMENTARY INFORMATION:

I. Summary of Major Changes and Economic Impact

The minimum wage and overtime pay requirements of the Fair Labor Standards Act (FLSA) are among the nation's most important worker protections. These protections have been severely eroded, however, because the Department of Labor has not updated the regulations defining and delimiting the exemptions for "white collar" executive, administrative and professional employees. By way of this rulemaking, the Department seeks to restore the overtime protections intended by the FLSA.

Under section 13(a)(1) of the FLSA and its implementing regulations, employees cannot be classified as exempt from the minimum wage and overtime requirements unless they are guaranteed a minimum weekly salary and perform certain required job duties. The minimum salary level was last updated in 1975, almost 30 years ago, and is only $155 per week. The job duty requirements in the regulations have not been changed since 1949-almost 55 years ago.

Revisions to both the salary tests and the duties tests are necessary to restore the overtime protections intended by the FLSA which have eroded over the decades. In addition, workplace changes over the decades and federal case law developments are not reflected in the current regulations. Under the existing regulations, an employee earning only $8,060 per year may be classified as an "executive" and denied overtime pay. By comparison, a minimum

wage employee earns about $10,700 per year. The existing duties tests are so confusing, complex and outdated that often employment lawyers, and even Wage and Hour Division investigators, have difficulty determining whether employees qualify for the exemption. The existing regulations are very difficult for the average worker or small business owner to understand. The regulations discuss jobs like key punch operators, legmen, straw bosses and gang leaders that no longer exist, while providing little guidance for jobs of the 21st Century.

Confusing, complex and outdated regulations allow unscrupulous employers to avoid their overtime obligations and can serve as a trap for the unwary but well-intentioned employer. In addition, more and more, employees must resort to lengthy court battles to receive their overtime pay. In the Department's view, this situation cannot be allowed to continue. Allowing more time to pass without updating the regulations contravenes the Department's statutory duty to "define and delimit" the section 13(a)(1) exemptions "from time to time."

Accordingly, on March 31, 2003, the Department published a Notice of Proposed Rulemaking (68 FR 15560) suggesting changes to the Part 541 regulations, including the largest increase of the salary levels in the 65-year history of the FLSA. The proposed changes to the duties tests were designed to ensure that employees could understand their rights, employers could understand their legal obligations, and the Department could vigorously enforce the law.

During a 90-day comment period, the Department received 75,280 comments from a wide variety of employees, employers, trade and

professional associations, small business owners, labor unions, government entities, law firms and others. In addition, the Department's proposal prompted vigorous public policy debate in Congress and the media. The public commentary revealed significant misunderstandings regarding the scope of the "white collar" exemptions, but also provided many helpful suggestions for improving the proposed regulations.

After carefully considering all of the relevant comments, and as detailed in this preamble, the Department has made numerous changes from the proposed rule to the final rule, including the following:

* * * *

II. Background

The FLSA generally requires covered employers to pay employees at least the federal minimum wage for all hours worked, and overtime premium pay of time-and-one-half the regular rate of pay for all hours worked over 40 in a single workweek. However, the FLSA includes a number of exemptions from the minimum wage and overtime requirements. Section 13(a) (1) of the FLSA provides an exemption from both minimum wage and overtime pay for "any employee employed in a bona fide executive, administrative, or professional capacity * * * or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary, subject to the provisions of the Administrative Procedure Act • * *)." 29 U.S.C. 213(a)(1).

Congress has never defined the terms "executive," "administrative," "professional," or

"outside salesman." Although section 13(a)(1) was included in the original FLSA enacted in 1938, specific references to the exemptions in the legislative history are scant. The legislative history indicates that the section 13(a)(1) exemptions were premised on the belief that the workers exempted typically earned salaries well above the minimum wage, and they were presumed to enjoy other compensatory privileges such as above average fringe benefits and better opportunities for advancement, setting them apart from the nonexempt workers entitled to overtime pay. Further, the type of work they performed was difficult to standardize to any time frame and could not be easily spread to other workers after 40 hours in a week, making compliance with the overtime provisions difficult and generally precluding the potential job expansion intended by the FLSA's time-and-a-half overtime premium. *See* Report of the Minimum Wage Study Commission, Volume IV, pp. 236 and 240 (June 1981).

Pursuant to Congress' specific grant of rulemaking authority, the Department of Labor has issued implementing regulations, at 29 CFR Part 541, defining the scope of the section 13(a)(1) exemptions. Because the FLSA delegates to the Secretary of Labor the power to define and delimit the specific terms of these exemptions through notice-and-comment rulemaking, the regulations so issued have the binding effect of law. *See Batterton v. Francis*, 432 U.S. 416, 425 n. 9 (1977).

The existing Part 541 regulations generally require each of three tests to be met for the exemption to apply: (1) The employee must be paid a predetermined and fixed salary that is not subject to reductions because of variations in the quality or

quantity of work performed (the "salary basis test"); (2) the amount of salary paid must meet minimum specified amounts (the "salary level test"); and (3) the employee's job duties must primarily involve executive, administrative or professional duties as defined by the regulations (the "duties tests").[1]

The major substantive provisions of the Part 541 regulations have remained virtually unchanged for 50 years. The FLSA became law on June 25, 1938, and the first version of Part 541 was issued later that year in October. 3 FR 2518 (Oct. 20, 1938). After receiving many comments on the original regulations, the Wage and Hour Division issued revised regulations in 1940. 5 FR 4077 (Oct. 15, 1940). *See also*, "Executive, Administrative, Professional * * * Outside Salesman" Redefined, Wage and Hour Division, U.S. Department of Labor, Report and Recommendations of the Presiding Officer (Harold Stein) at Hearings Preliminary to Redefinition (Oct. 10, 1940) ("1940 Stein Report"). The Department issued the last major revision of the duties test regulatory provisions in 1949. 14 FR 7705 (Dec. 24, 1949). Also in 1949, an explanatory bulletin interpreting some of the terms in the regulatory provisions was published as Subpart B of Part 541. 14 FR 7730 (Dec. 28, 1949). *See also*, Report and Recommendations on Proposed Revisions of

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[1] A number of states arguably have more stringent exemption standards than those provided by Federal law. The FLSA does not preempt any such stricter State standards. If a State or local law establishes a higher standard than the provisions of the FLSA, the higher standard applies. *See* Section 18 of the FLSA, 29 U.S.C. § 218.

Regulations, Part 541, by Harry Weiss, Presiding Officer, Wage and Hour and Public Contracts Divisions, U.S. Department of Labor (June 30, 1949) ("1949 Weiss Report"). In 1954, the Department issued the last major revisions to the regulatory interpretations of the "salary basis" test. 19 FR 4405 (July 17, 1954). After the initial minimum salary levels were set at $30 per week in 1938, the Department revised the Part 541 regulations to increase the salary levels in 1940, 1949, 1958, 1963, 1970 and 1975. 5 FR 4077 (Oct. 15, 1940); 14 FR 7705 (Dec. 24, 1949); 23 FR 8962 (Nov. 18, 1958); 28 FR 9505 (Aug. 30, 1963); 35 FR 883 (Jan. 22, 1970); 40 FR 7092 (Feb. 15, 1975). *See also*, Report and Recommendations on Proposed Revisions of Regulations, Part 541, under the Fair Labor Standards Act, by Harry S. Kantor, Presiding Officer, Wage and Hour and Public Contracts Divisions, U.S. Department of Labor (March 3, 1958) ("1958 Kantor Report").[2]

The framework of the existing Part 541 regulation is based upon the 1940 Stein Report, the 1949 Weiss Report and the 1958 Kantor report, which reflect the best evidence of the American workplace a half-century ago. The existing regulation, therefore, reflects the structure of the

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[2] Revisions to increase the salary rates in January 1981 were stayed indefinitely. 46 FR 11972 (Feb. 12, 1981). The Department also revised the regulations to accommodate statutory amendments to the FLSA in 1961, 1967, 1973, and 1992. 26 FR 8635 (Sept. 15, 1961); 32 FR 7823 (May 30, 1967); 38 FR 11390 (May 7, 1973); 57 FR 37677 (Aug. 19, 1992); 57 FR 46744 (Oct. 9, 1992).

workplace, the type of jobs, the education level of the workforce, and the workplace dynamics of an industrial economy that has long been altered. As the workplace and structure of our economy has evolved, so, too, must Part 541 be modernized to remain current and relevant. This necessary adaptation forms the philosophical underpinnings of this update and reflects the Department's efforts to remain true to the intent of Congress, which mandated that the DOL "from time to time" define and delimit these exemptions and the myriad terms contained therein.

The Department notes, however, that much of the reasoning of the Stein, Weiss and Kantor reports remains as relevant as ever. This preamble notes such instances, and articulates why the reasoning is still sound. However, while the Department carefully has reviewed these reports in undertaking this update, it is not bound by the reports. The Department is responsible for updating regulations that, with each passing decade of inattention, have become increasingly out of step with the realities of the workplace. Indeed, under this rulemaking, the Department is charged with utilizing record evidence submitted in 2003 * * * not in the 1940s or 1950s * * *in exercising its discretion to update the terms of this Part.

Suggested changes to the Part 541 regulations have been the subject of extensive public commentary for two decades, including public comments responding to an Advance Notice of Proposed Rulemaking issued by the Department in

November 1985,[3] a March 1995 oversight hearing by the Subcommittee on Workforce Protections of the Committee on Economic and Educational Opportunities, U.S. House of Representatives, a report issued by the General Accounting Office (GAO) in September 1999,[4] and a May 2000 hearing before the Subcommittee on Workforce Protections of the Committee on Education and the Workforce, U.S. House of Representatives. In its 1999 report to Congress and at the May 2000 hearing, the GAO chronicled the background and history of the exemptions, estimated the number of workers who might be included within the scope of the exemptions, identified the major concerns of employers and employees regarding the exemptions, and suggested possible solutions to the issues of concern raised by the affected interests. In general, the employers contacted by the GAO were concerned that the regulatory tests are too complicated, confusing, and outdated for the modern workplace, and create potential liability for violations when errors in classification occur. Employers were particularly concerned about potential liability for violations of the complex "salary basis" test, and complained that the "discretion and independent judgment" standard for administrative employees is confusing and applied inconsistently by the Wage and Hour Division. They also noted the traditional limits of the exemptions have blurred in the modern

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[3] 50 FR 47696 (Nov. 11, 1985).

[4] Fair Labor Standards Act: White Collar Exemptions in the Modern Work Place, GAO/HEHS-99-164, September 30, 1999 (GAO Report).

workplace. Employee representatives contacted by the GAO, in contrast, were most concerned that the use of the exemptions be limited to preserve existing overtime work hour limits and the 40-hour standard workweek for as many employees as possible. They believed the tests have become weakened as applied today by judicial rulings and do not adequately restrict employers' use of the exemptions. When combined with the low salary test levels, the employee representatives felt that few protections remain, particularly or low-income supervisory employees. The GAO Report noted that the conflicting interests affected by these rules have made consensus difficult and that, since the FLSA was enacted, the interests of employers to expand the white collar exemptions have competed with those of employees to limit use of the exemptions. To resolve the issues presented, the GAO suggested that employers' desires for clear and unambiguous regulatory standards must be balanced with employees' desires for fair and equitable treatment in the workplace. The GAO recommended that the Secretary of Labor comprehensively review the regulations and restructure the exemptions to better accommodate today's workplace and to anticipate future workplace trends.

Responding to the extensive public commentary, on March 31, 2003, the Department published proposed revisions to these regulations in the **Federal Register** inviting public comments for 90 days (*see* 68 FR 15560; March 31, 2003). In response to the proposed rule, the Department received a total of 75,280 comments during the official comment period. The Department received comments from a wide variety of individuals, employees, employers, trade and professional associations, labor unions,

governmental entities, Members of Congress, law firms, and others. Most of the comments received were form letters submitted by e-mail or facsimile. Form letters expressing general support of the proposal were received, for example, from members of the Society for Human Resource Management and from individuals who identified themselves as being in agreement with the HR Policy Association or the National Funeral Directors Association. More than 90 percent of the comments were form letters generated by organizations affiliated with the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) expressing general opposition to the proposal. These largely identical submissions raise concerns that the proposal would, for example, "diminish the application of overtime pay and seriously erode the 40 hour workweek" and lead to "[c]utting overtime pay" which "would really hurt America's working families." The form letters, however, do not address any particular aspect of the changes being proposed to the existing regulations. Indeed, some letters and emails appear to be from individuals who clearly perform non-exempt duties and are not covered by the Part 541 exemptions.

Approximately 600 of the comments include substantive analysis of the proposed revisions. Virtually all of these 600 comments favor some change to the existing regulations. Among the commenters there are a wide variety of views on the merits of particular sections of the proposed regulations. Acknowledging that there are strong views on the issues presented in this rulemaking, the Department has carefully considered all of the comments and the arguments made for and against the proposed changes.

The major comments received on the proposed regulatory changes are summarized below, together with a discussion of the changes that have been made in the final regulatory text in response to the comments received. In addition to the more substantive comments discussed below, the Department received some editorial suggestions, some of which have been adopted and some of which have not. A number of other minor editorial changes have been made to better organize or structure the regulatory text. Finally, a number of comments were received on issues that go beyond the scope or authority of these regulations (such as eliminating all exemptions from overtime, lowering the overtime threshold to fewer hours worked per week or per day, banning all mandatory overtime, and basing overtime on a twoweek/80-hour limit), which the Department will not address in the discussion that follows.

* * * *

Subpart F, Outside Sales Employees

Section 541.500 General Rule for Outside Sales Employees

Section 13(a)(1) of the FLSA contains a separate exemption for any employee employed "in the capacity of outside salesman." Proposed section 541.500 set forth the general rule for exemption of such "outside sales" employees.[11] Under proposed subsection 541.500(a), the outside sales exemption

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[11] Although the statute refers to "salesman," the final rule, without objection from commenters, replaces this gender-specific term with "outside sales employees."

applied to any employee "with a primary duty of (i) making sales within the meaning of section 3(k) of the Act, or (ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer." In addition, to qualify for exemption the outside sales employee must be "customarily and regularly engaged away from the employer's place or places of business in performing such primary duty." Finally, proposed subsection 541.500(b) stated that in determining the primary duty of an outside sales employee, "work performed incidental to and in conjunction with the employee's own outside sales or solicitations, including incidental deliveries and collections, shall be regarded as exempt outside sales work." Under this subsection, other work that furthers the employee's sales effort, including "writing sales reports, updating or revising the employee's sales or display catalogue, planning itineraries and attending sales conferences," is also considered exempt work.

The Department has retained this general rule as proposed.

The only modification intended in the proposed regulations was removing the restriction that exempt outside sales employees could not perform work unrelated to outside sales for more than 20-percent of the hours worked in a workweek by nonexempt employees of the employer. This revision was proposed for consistency with the "primary duty" approach adopted for the other section 13(a)(1) exemptions. In addition, the current outside sales 20-percent restriction is particularly complicated and confusing since it relies on the work hours of nonexempt employees and requires tracking the time

of employees who, by definition, spend much of their time away from the employer's place of business.

A large majority of the comments that address the outside sales exemption express support for the adoption of the "primary duty" test in lieu of the 20-percent rule. For example, the Society for Human Resource Management (SHRM) and Grocery Manufacturers of America (GMA) state that this revision would provide a more practical method for employers to determine whether an employee qualifies as an exempt outside sales employee. According to SHRM, in order to keep an account of the percentage of time that outside sales employees spend on exempt versus nonexempt tasks, as required under the 20-percent rule, employers essentially have to track the hours of their outside sales employees. SHRM notes that it is very difficult for employers to meet this responsibility given that outside sales employees spend large amounts of time away from their employers' regular places of business. GMA shares these concerns, stating that keeping track of an outside sales employee's individual activities to determine whether they are exempt, nonexempt or incidental to exempt sales activity is administratively difficult, if not impossible. The National Small Business Association comments that moving away from a percentage basis to the new definition of "primary duty" will alleviate much of the administrative burden on small business owners.

Two law firms commenting on the outside sales exemption (Goldstein Demchak Baller Borgen & Dardarian and McInroy & Rigby) ask the Department to retain the current 20-percent limit on nonexempt work. Both firms express concern that the outside sales exemption would be subject to

abuse by employers without a "bright-line" 20-percent test. In other words, employers might misclassify sales personnel as exempt under the outside sales exemption by merely requiring that they perform only minor amounts of outside sales work. A few commenters, such as the AFL-CIO, generally oppose removing the 20-percent limitation on nonexempt work for the same reasons discussed above in connection with the executive, administrative and professional exemptions.

After review of the relevant comments, the Department continues to believe that the application of the primary duty test to the outside sales exemption is preferable to the 20-percent tolerance test. As noted in several comments, the primary duty test is relatively simple, understandable and eliminates much of the confusion and uncertainty that are present under the existing rule. Cf. *Ackerman v. Coca-Cola Enterprises, Inc.*, 179 F.3d 1260, 1267 (10th Cir. 1999) (citing existing § 541.505(a) to the effect that "'[a] determination of an employee's chief duty or primary function must be made in terms of the basic character of the job as a whole' and that "the time devoted to the various duties is an important, but not necessarily controlling, element' "), *cert. denied*, 528 U.S. 1145 (2000). It also avoids the necessity that employers track the hours of its outside sales employees, which is consistent with the underlying rationale for exempting outside salespersons. Utilization of the primary duty concept also provides a consistent approach between the outside sales exemption and the exemptions for executive, administrative and professional employees. Finally, the Department is of the view that concerns relating to potential abuse under the new rule are addressed by the objective

criteria and factors for determining an employee's primary duty that are contained in section 541.700.

* * * *

Section 541.503 Promotion Work

Under proposed section 541.503, "promotional work" is exempt outside sales work if it "is actually performed incidental to and in conjunction with an employee's own outside sales or solicitations." However, "promotional work that is incidental to sales made, or to be made, by someone else is not exempt outside sales work." Proposed subsections 541.503(b) and 541.503(c) include examples to illustrate when promotional activities are exempt versus nonexempt work. To address commenter concerns discussed below, the Department has made minor changes to section 541.503(c).

* * * *

After reviewing the comments and current case law, the Department has made minor changes to section 541.503(c) to address commenter concerns that technological changes in how orders are taken and processed should not preclude the exemption for employees whose primary duty is making sales. As indicated in the proposal, the Department does not intend to change any of the essential elements required for the outside sales exemption, including the requirement that the outside sales employee's primary duty must be to make sales or to obtain orders or contracts for services. An employer cannot meet this requirement unless it demonstrates objectively that the employee, in some sense, has made sales. *See* 1940 Stein Report at 46 (outside sales exemption does not apply to an employee "who does not in some sense make a sale") (emphasis

added). Extending the outside sales exemption to include all promotion work, whether or not connected to an employee's own sales, would contradict this primary duty test. *See* 1940 Stein Report at 46 (outside sales exemption does not extend to employees "engaged in paving the way for salesmen, assisting retailers, and establishing sales displays, and so forth").

Nonetheless, the Department agrees that technological changes in how orders are taken and processed should not preclude the exemption for employees who in some sense make the sales. Employees have a primary duty of making sales if they "obtain a commitment to buy" from the customer and are credited with the sale. *See* 1949 Weiss Report at 83 ("In borderline cases the test is whether the person is actually engaged in activities directed toward the consummation of his own sales, at least to the extent of obtaining a commitment to buy from the person to whom he is selling. If his efforts are directed toward stimulating the sales of his company generally rather than the consummation of his own specific sales his activities are not exempt"). *See also Ackerman v. Coca-Cola Enterprises, Inc.*, 179 F.3d 1260, 1266-67 (10th Cir. 1999) (substantial merchandising responsibilities, including restocking of store shelves and setting up product displays, did not defeat outside sales exemption for soft drink advance sales reps and account managers where such responsibilities were "incidental to and in conjunction with" sales they consummated at stores they visited), *cert. denied*, 528 U.S. 1145 (2000); *Wirtz v. Keystone Readers Service, Inc.*, 418 F.2d 249, 261 (5th Cir. 1969) ("student salesmen" not exempt where engaged in

promotional activities incidental to sales thereafter made by others).

Exempt status should not depend on whether it is the sales employee or the customer who types the order into a computer system and hits the return button. The changes to proposed section 541.503(c) are intended to avoid such a result. Finally, the Department notes that outside sales employees may also qualify as exempt executive, administrative or professional employees if they meet the requirements for those exemptions. For example, an employee whose primary duty is promotion work such as advertising or marketing-not selling-may not meet the requirements for the "outside sales" exemption, but could be an exempt administrative employee.

APPENDIX M

No. 09-0437

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IN RE NOVARTIS
WAGE AND HOUR LITIGATION

On Appeal from the United States District Court
for the Southern District of New York

BRIEF FOR THE SECRETARY OF LABOR AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS

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No. 09-0437

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IN RE NOVARTIS
WAGE AND HOUR LITIGATION

On Appeal from the United States District Court
for the Southern District of New York

BRIEF FOR THE SECRETARY OF LABOR AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS

Pursuant to Federal Rule of Appellate Procedure 29, the Secretary of Labor ("Secretary") submits this brief as *amicus curiae* in support of the Plaintiffs-Appellants. The district court committed legal error when it concluded that the Plaintiffs-Appellants, Pharmaceutical Sales Representatives ("Reps") employed by Novartis Pharmaceutical Corporation ("NPC"), are exempt from the overtime requirements of the Fair Labor Standards Act ("FLSA" or "Act") under the "outside sales" exemption or, alternatively, the "administrative" exemption. *See* 29 U.S.C. 213(a)(1).

STATEMENT OF INTEREST OF THE SECRETARY OF LABOR

The Secretary administers and enforces the FLSA, *see* 29 U.S.C. 204(a) and (b), 211(a), 216(c), 217, and has a compelling interest in ensuring that it is interpreted correctly. By concluding that the Reps are exempt as outside salespersons despite the fact that they do not engage in any sales, the district court failed to follow the Department of Labor's ("Department's") regulatory provisions limiting the exemption to employees who make sales or obtain orders or contracts for services for which a consideration will be paid by the client or customer. *See* 29 C.F.R. 541.500. Moreover, the court's conclusion that the Reps, who are given lists of physicians to visit and are not allowed to go beyond the messages crafted by NPC (as set out in scripts and related materials with which they are provided), are exempt administrative employees is inconsistent with the regulatory requirement that employees must exercise discretion and independent judgment with respect to matters of significance in order to qualify for the administrative exemption. *See* 29 C.F.R. 541.200(a)(3).

STATEMENT OF THE ISSUES

(1) Whether the district court erred by concluding that the Reps are exempt outside salespersons despite the fact that they do not "make sales" as required by the Department's "outside sales" regulations.

(2) Whether the district court erred by concluding that the Reps are exempt administrative employees in accordance with the Department's "administrative exemption" regulations, which limit the exemption to employees who exercise discretion

and independent judgment with respect to matters of significance.

STATEMENT OF FACTS

The plaintiffs in this case are a class of over 2,500 Reps who worked for NPC in New York, California, and other states. The Food and Drug Administration ("FDA") prohibits Reps from selling drugs to physicians, *see In Re Novartis,* 593 F. Supp. 2d 637, 642 (S.D. N.Y. 2009); their primary duty is to call on physicians and provide them with information about NPC's drugs. *Id.* at 641. The goal of providing the physicians with this information is to convince them to prescribe NPC's drugs to their patients. Id.[1]

NPC trains the Reps in sales techniques as well as giving them basic training in pharmacology and other relevant subjects. *Id.* NPC expects the Reps to deliver a "core message" about the drugs to each physician, and provides them with scripts and other materials to help them do so. *Id.* They may not elaborate on the messages crafted by NPC, such as making claims about a drug's effectiveness, absent NPC authorization. *Id.* NPC also provides the Reps with materials to use in their presentations, such as pamphlets, clinical studies, and visuals aids, together with instructions on how these materials should be utilized; Reps may not use other materials

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[1] The patient does not purchase the prescribed drugs from a physician, but rather from a pharmacy. NPC sells its drugs directly to distributors, who in turn sell them to pharmacies, who then sell them to patients with prescriptions (Oral Argument Transcript, Nov. 18, 2008 at 5:9-10).

unless NPC has cleared them. *Id.*[2] Within these stringent parameters, the Reps "tailor" their presentations to each physician based on such considerations as the amount of time the physician is willing to meet with the Rep, the physician's patient base and prescribing habits, and the physician's personality. *Id.* at 642. NPC also provides the Reps with a budget for organizing informational events for their target physicians, following NPC guidelines for speakers and invitees. *Id.*

Each Rep is assigned a target list of physicians to call on; Reps may not remove or add physicians to their list without NPC's consent, and are reprimanded for failing to adhere to their target lists (Plaintiffs-Appellants' Statement of Facts ("SOF") at ¶¶ 37-40). NPC also assigns the Reps specific drugs to promote. *In Re Novartis*, 593 F. Supp. 2d at 641. Although NPC does not directly supervise the Reps, it expects them to call on a certain number of physicians on their list between 8 a.m. and 5 p.m. each weekday, determines how often Reps should call on each physician, and ranks each physician and drug in order of importance for each Rep (Plaintiffs-Appellants SOF at ¶ 37). *Id.* at 642. NPC also expects the Reps to "close" each physician visit by requesting a non-binding commitment to prescribe NPC drugs to their patients when appropriate or, in other cases, giving a physician a clinical study to review or thanking the physician for his time. *Id.*

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[2] If a Rep does not have a scripted response from NPC to a physician's concerns, she must try to "sidestep" the question by restating the "core message" or refer the physician to medical experts and NPC (Plaintiffs-Appellants SOF at ¶¶ 77-78).

The Reps earn an average annual "salary" of $91,500 that includes both base pay and "incentive payments" based on the number of prescriptions written by physicians. *Id.*

SUMMARY OF ARGUMENT

Under the Department's regulations, the Reps do not meet the requirements for either the outside sales or administrative exemption. The Reps do not sell or take orders for NPC's drugs; rather, they provide information to target physicians about NPC's drugs with the goal of persuading the physicians to prescribe those drugs to their patients. The actual sale of drugs takes place between NPC and pharmacies. Although the Reps' duties bear some of the indicia of sales -- they use methods of persuasion similar to those of salespersons, they receive some of their compensation. in the form of bonus or incentive payments, and their promotion work affects NPC's actual drug sales -- the fact that the Reps do not actually "make sales" conclusively demonstrates that the position is not that of an outside salesperson consistent with the Department's legislative rules.

Furthermore, when promoting the drugs to the physicians, the Reps are not permitted to deviate from the "core message" found in the scripts, manuals, brochures, and other materials NPC provides them. If the Reps do not have a scripted response to a physician's question, they are required to either reiterate the "core message" or refer the physician to NPC's medical experts. These constraints on the Reps' primary duties demonstrate that, although the Reps have some discretion (such as deciding what time of day to see which physician, tailoring their message to a physician's personality

or time constraints, and deciding whether to ask for a non-binding commitment at the end of a visit), they do not exercise discretion and independent judgment with respect to matters of significance. Thus, the Reps do not qualify for the administrative exemption.

ARGUMENT

I. THE DISTRICT COURT ERRED BY CONCLUDING THAT THE REPS ARE EXEMPT OUTSIDE SALESPERSONS DESPITE THE FACT THAT THEY DO NOT "MAKE SALES" AS REQUIRED BY THE DEPARTMENT'S "OUTSIDE SALES" REGULATIONS

Section 13(a)(1) of the FLSA provides a complete exemption from the overtime pay requirement for "any employee employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of outside salesman[,] as such terms are defined and delimited from time to time by regulations of the Secretary[.]" 29 U.S.C. 213(a)(1). The Act's "exemptions are to be narrowly construed against the employers seeking to assert them and their application limited to those [cases] plainly and unmistakably within their terms and spirit." *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392 (1960); *see Bilyou v. Dutchess Beer Distribs., Inc.*, 300 F.3d 217, 222 (2d Cir. 2002).

Pursuant to Congress's express delegation of rulemaking authority, the Secretary issued revised regulations after notice and comment that "define and delimit" the FLSA's overtime exemptions. *See* 69 Fed. Reg. 22,122 (Apr. 23, 2004). As such, they are entitled to controlling deference. *See Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843-44 (1984); *see also*

Long Island Care at Home, Ltd. v. *Coke*, 551 U.S. 158, 165-68, 171-74 (2007); *National Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005); *United States v. Mead* Corp., 533 U.S. 218, 229-30 (2001).[3]

1. As noted *supra*, section 13(a)(1) of the FLSA provides an exemption from the statute's minimum wage and overtime requirements for "any employee employed . . . in the capacity of outside salesman." The Department's regulations define that phrase as including "any employee . . . whose primary duty is . . . making sales within the meaning of section 3(k) of the Act, or . . . obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer." 29 C.F.R. 541.500(a)(1)(i)-(ii).[4] "Primary duty" means

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[3] To the extent that the plain language of the Department's outside sales or administrative regulations are ambiguous, courts must give controlling deference to the Department's interpretation of its own regulations unless such interpretation is plainly erroneous or inconsistent with those regulations. *See Federal Express Corp. v. Holowecki*, 128 S. Ct. 1147, 1155 (2008); Auer v. *Robbins*, 519 U.S. 452, 461 (1997). This principle holds true whether the Secretary's interpretation is found in a Preamble to a final rule published in the Federal Register, an opinion letter or other interpretive materials, or in a legal brief. *See, e.g., Coke*, 551 U.S. at 171 (controlling deference to Department's Advisory Memorandum issued during the course of litigation); *Auer*, 519 U.S. at 462 (controlling deference to legal brief).

[4] It is clear that the Reps are "customarily and regularly engaged away from" NPC's place of business. 29 C.F.R. 541.500(a)(2).

"the principal, main, major, or most important duty that the employee performs," 29 C.F.R. 541.700, and section 3(k) of the FLSA defines "sale" as "any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. 203(k); *see* 29 C.F.R. 541.501.[5] The Department's regulations further explain that "[s]ales within the meaning of section 3(k) of the Act include the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property," and that "services" "extends the outside sales exemption to employees who sell or take orders for a service, which may be performed for the customer by someone other than the person taking the order." 29 C.F.R. 541.501(b) and (d).

The regulations also explain the relationship between promotional work and the outside sales exemption, clarifying that

> [p]romotion work is one type of activity often performed by persons who make sales, which may or may not be exempt outside sales work, depending upon the circumstances under which it is performed. Promotional

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[5] Contrary to the conclusions of two recent district court decisions, the Reps' activities do not come within the "other disposition" language found in section 3(k). *See Schaefer-LaRose v. Eli Lilly & Co.*, S.D. Ind. No. 07-1133 (Sept. 29, 2009); *Delgado v. Ortho-McNeil, Inc.*, 2009 WL 2781525 (C.D. Cal. Feb. 6, 2009). The term "other disposition" must be read in the context of the language that precedes it, i.e., in the context of making some kind of a sale. The most the Reps can obtain is a non-binding commitment from a physician to prescribe NPC drugs as appropriate.

> work that is actually performed incidental to and in conjunction with an employee's own outside sales or solicitations is exempt work. On the other hand, promotional work that is incidental to sales made, or to be made, by someone else is not exempt outside sales work.

29 C.F.R. 541.503(a). In other words, "[p]romotion activities directed toward consummation of the employee's own sales are exempt. Promotional activities designed to stimulate sales that will be made by someone else are not exempt outside sales work." 29 C.F.R. at 541.503(b).

Thus, under the plain language of the Department's regulations, the Reps do not meet the primary duties test for the outside sales exemption.[6] Because the Reps do not sell any drugs or obtain any orders for drugs, and can at most obtain from the physicians a non-binding commitment to prescribe NPC's drugs to their patients when appropriate, the Reps do not meet the regulation's plain and unmistakable requirement that their primary duty must be "making sales." 29 C.F.R. 541.500(a)(1)(i). Contrary to the district court's assertion that "Reps

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[6] "A job title alone is insufficient to establish the exempt status of an employee. The exempt or nonexempt status of any particular employee must be determined on the basis of whether the employee's salary and duties meet the requirements of the regulations." 29 C.F.R. 541.2. Therefore, contrary to the district court's suggestion in *In Re Novartis*, 593 F. Supp. 2d at 654 n.7., the fact that NPC "hired, trained, paid, and incentivized [the Reps] as sales personnel" is not in any way dispositive.

make sales in the sense that sales are made" in the pharmaceutical industry, *In Re Novartis*, 593 F. Supp. 2d at 650, the actual sale of NPC's drugs occurs between the company and distributors (and then to the pharmacy).[7] Insofar as the Reps' work increases NPC's sales, it is non-exempt promotional work "designed to stimulate sales that will be made by someone else." 29 C.F.R. 541.503(b).

2. To the extent, however, that there is any ambiguity on this point in the Department's regulations, the Department's Wage and Hour Division has consistently reiterated its position that a "sale" for the purposes of the outside sales exemption requires a consummated transaction directly involving the employee for whom the exemption is sought.[8] For example, Wage and Hour

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[7] Even if it is true that absent a prescription no drugs would be sold to patients, *see In Re Novartis*, 593 F. Supp. 2d at 650, it nonetheless is "irrelevant to the dispositive inquiry of whether [Reps] make sales of those products as defined in the FLSA.". *Kuzinski, et al. v. Schering Corp.*, 604 F. Supp. 2d 385, 398 (D. Conn. 2009) (internal quotation marks omitted).

[8] In the context of addressing the "retail or service establishment" criteria of the FLSA's section 7(i) exemption, *see* 29 U.S.C. 207(i), Wage and Hour noted when discussing the definition of "sale" in section 3(k) of the FLSA that "[t]hough the term sale does not always have a fixed or invariable meaning, it is generally held to be a contract between parties to give and to pass rights of property for money, which the buyer pays or promises to pay to the seller for the thing bought or sold." WH Opinion Letter FLSA 2005-06, 2005 WL 330605 (citing *Wirtz v. Charleston Coca-Cola Bottling Company, Inc.*,

rejected the application of the outside sales exemption to individuals soliciting charitable contributions, noting that "[s]oliciting promises of future charitable donations or 'selling the concept' of donating to a charity does not constitute 'sales' for purposes of the outside sales exemption. . . . [These] solicitors do not obtain orders or contracts for services or for use of your client's facilities for which a consideration will be paid." WH Opinion Letter FLSA 2006-16, 2006 WL 1698305; see WH Opinion Letter August 19, 1994, 1994 WL 1004855 (concluding that soliciting organ and tissue donors by selling the concept of being a donor does not constitute "sales" under the regulations). Further, Wage and Hour's Field Operations Handbook ("FOH") states that "[an employee whose duty is to convince a dealer of the value of his employer's service to the dealer's customers and who does not in fact obtain firm orders or contracts from either the dealer or his customers is not making sales within the meaning of FLSA Sec. 3(k)." FOH § 22e04 (1965).

3. This Court has not addressed the question whether Reps are exempt as outside salespersons.[9]

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237 F. Supp. 857 (E.D.S.C. 1965)) (internal quotation marks omitted).

[9] No circuit court has addressed this specific question. There are, however, cases involving the application of the outside sales and administrative exemptions pending in the Third and Ninth Circuits. In *Smith* v. *Johnson & Johnson,* No. 09-1223, now before the Third Circuit on appeal, the district court determined that the outside sales exemption does not apply to Reps because they do not "make sales," but that they

Within the Second Circuit, the district courts that have addressed the question have, with the exception of the decision in the instant case, concluded that the outside sales exemption does not apply to Reps because they do not make sales as required by the Department's regulations. *See Kuzinski,* 604 F. Supp. 2d at 403 ("Because [the Reps] undisputedly do not sell or make any sales as those terms are defined in the FLSA and its implementing regulations, they fall outside the FLSA's outside sales exemption.") (internal quotation marks omitted); *Ruggeri v. Boehringer Ingelheim Pharmaceuticals, Inc.,* 585 F. Supp. 2d 254, 272 (D. Conn. 2008) ("Because [the pharmaceutical company] has not shown that [the Reps] make sales or obtain contracts or orders, the outside sales exemption is inapplicable."); *Amendola v. Bristol-Myers Squibb Co.,* 558 F. Supp. 2d 459, 470 (S.D.N.Y. 2008) ("As a starting point, the

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are exempt administrative employees who exercise discretion as to matters of significance. *See Smith v. Johnson & Johnson,* 2008 WL 5427802, at *11-12 (D. N.J. Dec. 30, 2008). Currently before the Ninth Circuit are two cases in which the Central District of California concluded that Reps are exempt as outside salespersons. *See Yacoubian v. Ortho-McNeil Pharmaceutical Corp.,* Ninth Cir. No. 09-55225 (No. 07-127, C.D. Cal. Feb. 6, 2009); *Delgado v. Ortho-McNeil Primary Care, Inc.,* Ninth Cir. No. 09-55229 (No. 07-263, C.D. Cal. Feb. 6, 2009); *cf. D'Este v. Bayer Corp.,* 565 F.3d 1119 (9th Cir. 2009) (certifying to California Supreme Court the question whether the Central District of California correctly concluded that Reps are exempt outside salespersons under California state law; the district court's decisions relied in part on its interpretation of the FLSA's requirements).

interpretation of the [FLSA outside sales] exemption rests on the plain meaning of the statutory and regulatory texts that define it.").

The district court here relied upon this Court's statement in an FLSA "salary basis" case that "[g]iven the broad scope of the FLSA and its implementing regulations, [the Department's] regulations provide only general guidance to accommodate the varying needs of employers and employees in a diverse and varied national economy," *see Havey v. Homebound Mortgage, Inc.*, 547 F.3d 158, 163 (2d Cir. 2008), for its conclusion that it could "take[] into account the characteristics of the industry in question when determining the applicability of the outside sales exemption." *In Re Novartis*, 583 F. Supp. 2d at 649. As noted by the district court in *Kuzinski*, however, "that observation . . . does not mean that an exemption to an employer's obligation to pay overtime under the FLSA can apply more broadly than the regulations specify." 604 F. Supp. 2d at 397 (internal quotation marks omitted).[10] "The conclusion that [Reps] fall within the outside sales exemption from FLSA's overtime provisions on the basis of the characteristics of the industry in question . . . notwithstanding [the Reps'] lack of capacity to sell,

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[10] This Court, despite referring to the "general guidance" provided by the regulations, did not ignore what the regulations plainly and specifically prescribe. *See Havey*, 547 F.3d at 163-64 ("[T]he regulations specify that a salaried employee must be paid a fixed and predetermined amount . . . but do not prescribe when or how frequently this fixed element of compensation may be determined . . . .").

and physicians' lack of capacity to purchase" is an attempt at "back-fitting . . . the FLSA to industry practices." *Id.* at 399 (internal quotation marks omitted); *see Ruggeri*, 585 F. Supp. 2d at 267 ("The justification for the pharmaceutical industry's use of [Reps] and direction of their efforts at physicians based on the artifact of medical and drug regulation . . . does not provide justification for applying the outside sales exemption to [the Reps], especially given that FLSA exemptions apply only to those employees who are plainly and unmistakably within them.") (internal quotation marks omitted).

As noted by the Tenth Circuit, "[t]he touchstone for making a sale, under the [Department's regulations], is obtaining a commitment." *Clements v. Serco*, 530 F.3d 1224, 1227 (2008) (concluding that civilian military recruiters are not within the outside salesperson exemption even though they "engaged in sales training and 'sold' the idea of joining the Army to potential recruits," because they did not engage in sales work as defined by the Department's regulations). In a similar situation to that presented here, the district court in *Kuzinski* concluded:

> [T]he closest that [Reps] come to consummating "sales" is increasing the overall demand for its products, such that [other company] employees negotiate and commit to contracts with wholesalers -- not the physicians to whom [the company's] products are promoted. An employee does not consummate a "sale" for purposes of the FLSA merely by "lay[ing] the groundwork" for another employee to obtain a customer's commitment. ... . To the extent [the Reps] lay foundation or groundwork, it is to increase or maintain their employer's market share for

> the products they promote. In this sense they pave the way for sales but in no more direct a manner as a pharmaceutical company's direct-to-consumer advertising, which raises demand for that company's products. Neither of these activities constitutes "sales" under the FLSA.

604 F. Supp. 2d at 399 (citing *Clements*, 530 F.3d at 1229).

4. The cases cited by the district court as support for its conclusion that the Reps "make sales" are inapposite. In *Gregory v. First Title of America, Inc.*, 555 F.3d 1300, 1308-10 (2009), the Eleventh Circuit concluded that a "Marketing. Director" was an exempt outside salesperson because she obtained orders for title insurance services. In contrast to the instant case, there was no "evidence of any other intervening sales effort between [the Marketing Director] and orders placed with [her employer]"; once she obtained the order for title insurance services, the sale was complete. *Id.* at 1309. The First Circuit case cited by the district court, *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 47 (2008), *cert. denied*, 129 S.Ct. 2864 (2009), involved the question whether Reps (which that court referred to as "detailers") were entitled to access to "patient-identifiable and prescriber-identifiable data" about prescriptions written in New Hampshire. Although the First Circuit referred to the Reps effect in increasing the pharmaceutical companies' market share, the question of pharmaceutical sales, in relation to the FLSA or any other law, was not before it. Similarly, although the district court in *Medtronic, Inc. v. Gibbons*, 527 F. Supp. 1085 (D. Minn. 1981), *aff'd*, 684 F.2d 565 (8th Cir. 1982), described the employees of cardiac pacemaker

manufacturers who promoted the pacemakers to physicians as "sales representatives" and their work in terms of "sales," the issue implicated in that case was a covenant not to compete, not the FLSA's outside sales exemption. *Id.* at 109495. The court was interpreting the term "customer" under applicable contract construction (*i.e.*, the customers with whom Gibbons had contact in the year immediately preceding his employment with the employer), not the term "sale" under the FLSA or, more specifically, what is required before an employer may avail itself of the outside sales exemption.

II. THE DISTRICT COURT ERRED BY CONCLUDING THAT THE REPS ARE EXEMPT ADMINISTRATIVE EMPLOYEES IN ACCORDANCE WITH THE DEPARTMENT'S "ADMINISTRATIVE EXEMPTION" REGULATIONS, WHICH LIMIT THE EXEMPTION TO EMPLOYEES WHO EXERCISE DISCRETION AND INDEPENDENT JUDGMENT WITH RESPECT TO MATTERS OF SIGNIFICANCE

1. The employer failed to show that the Reps exercise discretion and independent judgment with respect to matters of significance. Under the Department's administrative exemption regulations, an "employee employed in a bona fide administrative, capacity" means "any employee . . . whose primary duty is the performance of office or non-manual work directly related to the management or general business operations of the employer or the employer's customers . . . [and] . . .

[w]hose primary duty includes the exercise of discretion and independent judgment with respect to matters of significance." 29 C.F.R. 541.200(a)(2)-(3).[11] The requirement that the employee's primary duty include the exercise of discretion and independent judgment "involves the comparison and the evaluation of possible courses of conduct, and acting or making a decision after the various possibilities have been considered. The term 'matters of significance' refers to the level of importance or consequence of the work performed." 29 C.F.R. 541.202(a). Furthermore, the phrase "discretion and independent judgment" must be applied in the light of all the facts involved in the particular employment situation, with the following factors to be considered:

> whether the employee has authority to formulate, affect, interpret, or implement management policies or operating practices; whether the employee carries out major assignments in conducting the operations of the business; whether the employee performs work that affects business operations to a

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[11] In order to fall within the administrative exemption, the employee must also meet the salary requirement of $455 per week. *See* 29 C.F.R. 541.200(a)(1). The salary requirement is not at issue in this case. Further, because the Reps do not satisfy the "discretion and independent judgment with respect to matters of significance" prong of the administrative exemption, this brief does not address whether the Reps' "primary duty is the performance of office or non-manual work directly related to the management or general business operations of the employer or the employer's customers." 29 C.F.R. 541.200(a)(2) and (3).

> substantial degree, even if the employee's assignments are related to operation of a particular segment of the business; whether the employee has authority to commit the employer in matters that have significant financial impact; whether the employee has authority to waive or deviate from established policies and procedures without prior approval; whether the employee has authority to negotiate and bind the company on significant matters; whether the employee provides consultation or expert advice to management; whether the employee is involved in planning long or short-term business objectives; whether the employee investigates and resolves matters of significance on behalf of management; and whether the employee represents the company in handling complaints, arbitrating disputes or resolving grievances.

29 C.F.R. 541.202(b).[12] Although this list is not exhaustive, it indicates the kind of activities that constitute "matters of significance."

Moreover, the exercise of discretion and independent judgment must be more than the use of skill in applying well- established techniques, procedures, or specific standards described in

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[12] As the Preamble to the final rule, 69 Fed. Reg. 22,143 (Apr. 23, 2004), explained, federal courts generally find that employees who meet at least two or three of the indicators mentioned in 29 C.F.R. 541.202(b) are deemed to be exercising discretion and independent judgment with respect to matters of significance, although a case-by-case analysis is required.

manuals or other sources. *See* 29 C.F.R. 541.202(e); *see also* 541.203(g)-(i) (clarifying through examples of exempt and non-exempt administrative employees that reliance on techniques and skills developed through specialized training and use of manuals is insufficient for application of the exemption). The regulations also clarify that "[a]n employee does not exercise discretion and independent judgment with respect to matters of significance merely because the employer will experience financial losses, if the employee fails to perform the job properly." 29 C.F.R. 541.202(f).

2. Wage and Hour has consistently reiterated that both the nature and level of the employee's decisions as they relate to the employer's business operations determine whether the employee exercises discretion and independent judgment with respect to matters of significance. "In this regard, it is not sufficient that an employee makes decisions regarding when and where to do different tasks, as well as the manner in which to perform them." WH Opinion Letter FLSA 2006-45, 2006 WL 3930478 (copy editors do not exercise discretion as to matters of significance even though they "organize work priorities to meet production deadlines set by management [and] make decisions on workflow within their areas and communicate these decisions to club copywriters") (citing *Clark v. J.M. Benson Co.*, 789 F.2d 282, 287 (4th Cir. 1986)) (internal quotation marks omitted). Another Wage and Hour opinion letter from 2006, denying the application of the administrative exemption to legal analysts, provides a helpful analogous example:

> Although you state that you work independently and use your own judgment as to how to prioritize your work assignments, including how the projects will be executed and how much time to spend on each assignment, it is not sufficient that an employee makes decisions regarding relatively insignificant matters . . . Nor is it sufficient that an employee makes limited decisions, within clearly "prescribed parameters." *See Dalheim v. KDFW-TV,* 706 F. Supp. 493, 509 (N.D. Tex. 1998), *aff'd,* 918 F.2d 1220 (5th Cir. 1990). Rather, there must be the exercise of discretion and independent judgment on matters of significance or consequence related to the management or general business operations of the employer or the employer's customers. For instance . . . you do not formulate or implement management policies, utilize authority to waive or deviate from established policies, provide expert advice, or plan business objectives in accordance with the dictates of § 541.202(b).

WH Opinion Letter FLSA 2006-27, 2006 WL 2792441.[13]

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[13] Wage and Hours' opinion letter on legal analysts also demonstrates that regulatory or legal limitations on an employee's exercise of discretion are, in fact, limitations that may preclude application of the administrative exemption: "In addition, most jurisdictions have strict prohibitions against the unauthorized practice of, law by laypersons. . . . The implication of such strictures is that paralegal employees would not have

Much like the legal analysts, Reps work independently (i.e., without direct supervision), determine what time of day to visit the physicians on their lists, and decide how best to execute their presentations within clearly prescribed parameters. This, however, similarly does not suffice to qualify for the administrative exemption; the Reps do not perform any primary duties that are largely comparable to those found in 29 C.F.R. 541.202(b), such as formulating or implementing management policies, utilizing authority to deviate from established policies, providing expert advice, or planning business objectives.[14] *Compare* WH Opinion

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the amount of authority to exercise independent judgments with regard to legal matters necessary to bring them within the administrative exemption." WH Opinion Letter FLSA 2006-27. Similarly, there are legal constraints placed on the Reps. "Since the Reps are advocating products which are routinely and closely regulated by the Food and Drug Administration (FDA), NPC prepares scripts and related materials which the Reps are expected to use to deliver a 'core message' about NPC products to each physician they visit; Reps may not go beyond the boundaries of the messages crafted by NPC." *In Re Novartis* 593 F. Supp. 2d at 641.

[14] The cases set out in the Preamble to the 2004 Part 541 regulations to support the factors listed in 29 CF.R. 541.202(b) clearly refer to the kind of work not engaged in by the Reps here -- making recommendations to management on policies and procedures; conducting independent investigation and resolution of issues without prior approval; having authority to waive or deviate from established policies and procedures without prior approval; developing guidebooks, manuals, and other policies and procedures for the employer or the employer's

Letter FLSA 2006-34, 2006 WL 3227789 (applying administrative exemption to community events supervisors because their authority to negotiate and bind their employers on significant matters such as negotiating contracts with vendors was sufficient to demonstrate discretion and independent judgment with respect to matters of significance); WH Opinion Letter FLSA 2006-46, 2006 WL 3930479 (location managers' primary duties, such as creating and enforcing regulations for the production crew, committing the employer in financial matters, and negotiating site rentals, included the exercise of discretion and independent judgment as to matters of significance).

3. No circuit court has addressed whether Reps are exempt administrative employees. Besides the instant case, one district court within the Second Circuit, relied upon by the district court in *In Re Novartis,* 593 F. Supp. 2d at 656-58, has concluded that the "discretion and independent judgment with respect to matters of significance" test for the administrative exemption "likely" applies to Reps because their daily decisions (which are similar to those in this case) "seek to influence prescription writing practices -- a matter of great consequence to [their employer's] business" -- and their "exercises of judgment [are] ways to drive the business [and] move market share," and because "if the doctor didn't like [the Rep], then the doctor was not going to prescribe

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customers; negotiating on behalf of the employer with some degree of settlement authority; having authority to commit employer in matters that have financial impact. *See* 69 Fed. Reg. 22,143-144 (April 23, 2004).

the drug." *Amendola,* 558 F. Supp. 2d at 477. At issue in *Amendola,* however, was the plaintiff Rep's motion for discovery of the names and addresses of the pharmaceutical company's Reps, authorization for notice of the collective action to be sent to those potential plaintiffs, and equitable tolling of any claims they may file. *See* 558 F. Supp. 2d at 462. As such, the district court looked only at the "likelihood" that the pharmaceutical company would successfully argue the application of the administrative exemption to the Reps when deciding whether to grant the plaintiff's motion. *Id.* at 477.

Furthermore, the district court in *Amendola* relied in part on a 1945 Wage and Hour opinion letter which concluded that drug companies' "medical detailists" were administratively exempt. Those medical detailists, though, "were consulted with respect to individual nutritional problems encountered by hospitals and physicians, such as determining whether the use of subject's product was related to the occurrence of an epidemic," and "work[ed] virtually without supervision." *Ruggeri,* 585 F. Supp. 2d at 276 (internal quotation marks omitted). In addition, the court's analysis appears to have misunderstood the "matters of significance" requirement. In commenting on "driving the business" and "market share," it blurred the distinction between an employee who exercises discretion and independent judgment related to matters of significance and one whose skillful job performance necessarily has some impact on her employer's bottom line (something undoubtedly

important to the company).[15] *See, e.g., Robinson-Smith v. Government Employees Insurance Co.*, 323 F. Supp. 2d 12, 25 (D. D.C. 2004) (noting, in the course of concluding that auto damage adjusters,

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[15] In addition to the decision in *Amendola*, the district court in the instant case relied heavily on another district court case, *Cote* v. *Burroughs Wellcome Co.*, 558 F. Supp. 883 (E.D. Pa. 1982), as persuasive authority for concluding that the Reps are exempt administrative employees. In *Cote*, the court concluded that a Rep exercised sufficient discretion for the administrative exemption to apply because, even though she worked within a tightly-controlled marketing environment, the Rep could tailor her presentation to individual doctors in terms of her manner and the frequency of her visits and could "cultivat[e] a good working relationship with the nurses at a particular clinic and asking for their help in reminding physicians about the drug." 558 F. Supp. at 887. As a threshold matter, contrary to the district court's reasoning in *Ruggeri*, 585 F. Supp. 2d at 276, the fact that *Cote* was decided under the "old" Part 541 regulations does not vitiate its reasoning. *See* 69 Fed. Reg. 22,143 (April 23, 2004) (making the phrase "matters of significance" part of the regulatory test for the administrative exemption instead of having it as part of the Department's interpretive guidance). Nevertheless, the analysis in *Cote* fails for all the reasons set out *supra*. "Tailoring" one's strictly circumscribed presentations and establishing good personal working relationships do not equate to primarily performing duties requiring the exercise of discretion and independent judgment concerning matters of significance. Of course, as district court decisions, neither *Amendola* nor *Cote* is controlling vis-à-vis this Court. *See Lombard v. Whitman*, 485 F.3d 73, 83 (2d Cir. 2007) (distinguishing between own precedent and district court decisions).

who assess, negotiate, and settle automobile damage claims, travel to and from inspection sites, inspect vehicles for damage, and write estimates for repairs were not exempt, that "'the use of skill is to be clearly distinguished from work requiring discretion and independent judgment'") (quoting *Reich v. American Int'l Adjustment Co.*, 902 F. Supp. 321, 324 (D. Conn. 1994)). As noted by the Department's regulations, an employee does not exercise discretion and independent judgment related to matters of significance merely because his success (or lack thereof) in performing his duties has a financial impact on his employer's business. *See* 29 C.F.R. 541.202(f); *see also Ruggeri*, 585 F. Supp. 2d at 276 n.13 (when denying summary judgment to pharmaceutical company on the question of whether its Reps were exempt administrative employees, the court rejected the argument that the exemption applied because of Reps' impact on company's financial success). Indeed, if the "matters of significance" standard were interpreted to include any actions that in some manner "move market share" or "drive the business," it would potentially broaden the exemption to include the host of employees whose successful performance of their duties contributes in some way to the success of the company; such an interpretation would effectively swallow the "rule" requiring the payment of the minimum wage and overtime compensation under the FLSA.[16]

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[16] It is worth noting that the district court in *In Re Novartis* did not rely upon the First Circuit's decision in *Reich v. John Alden Life Insurance Company*, 126 F.3d 1, 9 (1st Cir.

4. In sum, as with the outside sales exemption, the district court's administrative exemption ruling in this case is unpersuasive in its attempt to "back-

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1997), to show that the Reps exercised discretion and independent judgment concerning matters of significance; rather, it used *Alden* to show that the Reps performed office or non-manual work directly related to management or general business operations. *See* 593 F. Supp. 2d at 655-58. In any event, the decision in *Alden* can be distinguished on its facts. In *Alden,* marketing representatives working for a company that designed, created, and sold insurance products (primarily for businesses that were purchasing group coverage for their employees) did not sell through direct contacts with the ultimate consumers but, rather, relied upon licensed independent insurance agents to make sales of the employer's financial products. The marketing representatives were responsible for maintaining contact with hundreds of these independent sales agents to keep them apprised of the employer's financial products, inform them of changes in prices, and discuss how the product might fit their customer's needs (they would also inform the employer of what they learned from these agents, e.g., regarding a competitor's products or pricing). The First Circuit concluded that these marketing representatives were administratively exempt. Significantly, however, the First Circuit, in concluding that the discretion and independent judgment prong was met, noted that the marketing representatives "do not use prepared scripts or read from a required verbatim statement, nor do they operate within the contours of a prescribed technique or 'sales pitch.'" *John Alden Life Ins. Co.,* 126 F.3d at 14. By contrast, the Reps in the instant case are provided with scripts, which they are required to use, to help them deliver the requisite "core message." *In Re Novartis,* 593 F. Supp. 2d at 641.

fit" the FLSA regulations into the pharmaceutical industry's practices. The facts are clear that, within the stringent restrictions on Reps' work activities, the Reps' discretion is limited to such matters as what time of day to visit a particular doctor, the manner in which to approach the doctor based on the doctor's personality, and how best to deliver (i.e., to "fit in") the NPC's "core message" for a particular drug given the time constraints of a visit. To the extent that the Department's administrative exemption regulations instruct that "[t]he phrase 'discretion and independent judgment' must be applied in the light of all the facts involved in the particular employment situation in which the question arises," *see* 29 C.F.R. 541.202(b), this guidance does not extend to ignoring the clear parameters and requirements of the regulations. *See, e.g., Kuzinski,* 604 F. Supp. 2d at 397-99. The Seventh Circuit's decision in *Kennedy v. Commonwealth Edison Co.,* 410 F.3d 365, 374-75 (2005), although analyzing the pre-2004 regulations, provides a useful comparison of what constitutes the exercise of discretion related to matters of significance within a highly regulated industry. In *Kennedy,* the Seventh Circuit concluded that, despite the heavily regulated nature of the nuclear power industry, work planners whose "job is to come up with a set of instructions that will remedy reported problems around the plant" were exempt. Even though the planners "look to past work packages for guidance and use a computer to aid their recommendations . . . [when] [f]aced with novel or not-so-novel problems, judges and Work Planners must use their independent judgment to determine how best to respond." *Id.* The work planners, although heavily regulated, thus had the discretion to develop new ways to resolve issues. The NPC

Reps, on the other hand, do not have such discretion; NPC provides them with specific instructions for each aspect of their job, including scripted responses for physician concerns, from which NPC does not permit them to deviate. They therefore should not be deemed to exercise discretion and independent judgment regarding matters of significance.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's decision.

Respectfully submitted,

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In The Supreme Court of the United States

SCHERING CORPORATION,

Petitioner,

v.

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, and SHAWN JONES, on behalf of themselves and others similarly situated,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

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QUESTION PRESENTED

Did the district court and court of appeals err in denying summary judgment to petitioner on its affirmative defense because respondents – pharmaceutical representatives who visit doctors and attempt to persuade them to write prescriptions for Schering products sold to consumers by pharmacies – were not plainly and unmistakably exempt from the FLSA as "outside salesm[e]n," 29 U.S.C. § 213(a)(1)?

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STATEMENT OF THE CASE

A. Introduction

After accepting and hearing Petitioner's permissive interlocutory appeal pursuant to 28 U.S.C. § 1292(b), the court of appeals issued a summary order (Pet. App. 1a-4a) affirming the denial of "summary judgment for the reasons stated in the district court's ruling and for the reasons stated in [its] opinion in *In re Novartis Wage Litig.*, [611 F.3d 141 (2d Cir. 2010) (Pet. App. 45a-78a)]."[1] (Pet. App. 3a).

Now Schering petitions for a writ of certiorari, but it ignores all traditional criteria for evaluating such a petition. Sup. Ct. R. 10. Petitioner contends that the courts below and the Department of Labor ("DOL") incorrectly interpreted the Fair Labor Standards Act ("FLSA") and the DOL's own statutorily authorized regulations, in a manner that "changed the definition of the [outside sales] exemption itself." (Pet. 2).

Petitioner's argument is as procedurally misguided as it is wrong. It is belied by seventy years of consistent, unambiguous regulatory actions and activities undertaken by the DOL, which consistently

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[1] The court of appeals heard and considered the appeal in this case "in tandem with the appeal in *In re Novartis*," and decided both appeals the same day. *Id.* Novartis filed a petition for certiorari on the same day as Schering, Docket No. 10-460. The opinion in *In re Novartis* is reproduced in the petition appendix. (Pet. App. 45a-78a).

confirm the crucial distinction between: (1) employees who work outside of an office and are engaged directly in consummating the sale or exchange of goods and services between their employers and consumers; and (2) those who do not themselves "make sales," but instead are engaged in activities designed to promote and encourage sales of their employer's products. *See* 29 C.F.R. § 541.503(a)-(c). The courts below did not err. The parameters of the outside sales exemption have not changed.

Petitioner also claims this Court's "guidance" is needed to "clarify" the "scope" of deference paid to the DOL's interpretation of its own regulations under *Auer v. Robbins*, 519 U.S. 452 (1997). The only thing that petitioner identifies as warranting clarification, however, is "the extent to which *Auer* deference" applies to a "change in agency interpretation" announced for the first time in an *amicus* brief." Pet. 15. This makes no sense. It assumes that "guidance" is needed in circumstances – not presented here – where an agency's interpretation of its regulations is inconsistent with the regulations themselves or prior agency interpretations. But, *Auer*, of course, addresses these exact circumstances. *Auer* teaches that an agency interpretation, whether in an *amicus* brief or somewhere else, is accorded controlling deference unless it is "inconsistent" with the agency's regulations or plainly erroneous. 519 U.S. at 461.

Auer needs no "clarification." The problem for petitioner is that the prerequisites for according controlling deference set forth in *Auer* are plainly

satisfied in this case. The DOL's interpretation of its own implementing regulations concerning the outside sales exemption have been a model of uniformity and consistency for more than seventy years. Thus, like its error correction argument, petitioner's argument that there is something wrong with *Auer* should be swiftly rejected.

The courts below properly concluded that respondents were not plainly and unmistakably engaged in "making sales" within the meaning of the FLSA and its implementing regulations. The decisions were not in error. There is no basis for issuing a writ of certiorari.

B. Statutory and Regulatory Framework

Under the FLSA, an employer bears the burden of proving that an employee is employed "in the capacity of an outside salesman" in order to treat that employee as exempt from overtime and minimum wage pay requirements. 29 U.S.C. § 213(a)(1). The FLSA specifies that the term "outside salesman" is to be interpreted as it is "defined and delimited from time to time by regulations of the Secretary [of Labor]." *Id.* The Secretary's regulations define an "outside salesman" as an employee whose primary duty is "making sales within the meaning of section 3(k) of the [FLSA] or . . . obtaining orders or contracts for services or for the use of facilities for which consideration will be paid by the client or customer; and . . . [w]ho is customarily and regularly engaged away

from the employer's place or places of business when performing such primary duty." 29 C.F.R. § 541.500(a).

A "sale" is defined in the statute and regulations to require an exchange of goods or services for valuable consideration. Section (3)(k) of the FLSA defines sales to include "any sale, exchange, contract to sell, consignment for sale, shipment for sale or other disposition." 29 U.S.C. § 203(k). The regulations further specify that sales under the act involve the "transfer of title to tangible property, and in certain cases tangible and valuable evidence of intangible property." 29 C.F.R. § 541.501(b).

The regulations draw a bright line distinction between non-exempt promotional work and exempt sales work.[2] "Promotional work that is actually performed incidental to and *in conjunction with an employee's own outside sales*" may be exempt work under the outside sales exemption (assuming that other elements of the exemption are met). 29 C.F.R. § 541.503(a) (emphasis supplied). "[P]romotional work that is *incidental to sales made, or to be made, by someone else* is not exempt outside sales work." *Id.* (emphasis supplied).

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[2] "[Congress] use[d] the word 'delimited' as well as the word 'defined,'" thus the Department of Labor "is responsible not only for determining which employees are entitled to the exemption, but also for drawing the line beyond which the exemption is not applicable." *See* 1940 Stein Report, at 22 (Oct. 10, 1940).

The regulations also provide instructive examples of how the promotional/sales distinction works. One example discusses a manufacturer's representative who performs a variety of promotional tasks aimed at making his employer's products attractive and desirable to purchasers: "such an employee can be considered an exempt outside sales employee if the employee's primary duty is making sales or contracts. Promotional activities directed towards consummation of the employee's *own sales* are exempt. *Promotional activities designed to stimulate sales that will be made by someone else are not exempt outside sales work.*" 29 C.F.R. § 541.503(b) (emphasis supplied). Another example, dealing with company representatives who visit chain stores to monitor merchandise inventory, similarly notes that "[b]ecause the employee in this instance does not *consummate the sale* . . . the work is not exempt outside sales work." *Id.* at § 541.503(c) (emphasis supplied).[3]

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[3] Opinion Letters issued by the DOL over the years reinforce the distinction between promoting a product or service and actually consummating a sale. *See* 2006 DOLWH LEXIS 65, at *5 ("Soliciting promises of future charitable donations or 'selling the concept' of donating to a charity does not constitute 'sales' for purposes of the outside sales exemption."); 1998 DOLWH LEXIS 17, at *7 (a college recruiter was not an outside sales person where he "is engaged in identifying qualified customers, i.e., students, and inducing their application to the college, which in turn decides whether to make a contractual offer of its educational services to the applicant."); 1994 DOLWH LEXIS 65 ("Selling [the] concept [of donating human tissues] does not constitute 'sales' within the meaning of the regulations" and neither is "buying into the merits" of a product).

C. Schering's Business and Respondents' Jobs

"Schering manufactures and 'sells prescription drugs to hospitals, certain managed care organizations, wholesale distributors and retail pharmacists.' It employs . . . pharmaceutical sales representative[s] ('PSR[s]') – through whom it 'introduces and makes known its prescription drugs to physicians, pharmacists, hospitals, managed care organizations and buying groups.'" (Pet. App. 6a) (citations omitted).

Schering does not sell products directly to consumers. Instead, over 90 percent of Schering's products are sold "to wholesalers, and the remainder go to governmental entities, hospitals, and directly to chain pharmacies." (Pet. App. 7a) (citation omitted). Schering's primary customers – wholesalers – "negotiate 'inventory management agreements,' which limit their inventory levels and set prices on Schering's products, with the 'trade organization' and 'legal team' operating under Schering's managed markets group." (Pet. App. 7a-8a) (citations omitted). PSRs are not in the managed markets group and have no involvement with negotiating the agreements that establish the pricing and quantity of Schering's products. (Pet. App. 8a).

"Schering does not record income when a health care provider tells a PSR that he or she will consider using a Schering product or prescribing a Schering product, or promises a PSR that he or she will prescribe a Schering product, or commits to a PSR that he or she will prescribe a Schering product, or writes

a prescription for a Schering product." (Pet. App. 8a) (citations, internal quotation marks and brackets omitted). Nor does Schering record income when a doctor "hands a prescription to a patient, or when the prescription is filled at a pharmacy, or when a patient pays for a prescription at a pharmacy, or when an insurance company reimburses a pharmacy for a prescription for a Schering product that is filled by a patient." (Pet. App. 8a) (citations, internal quotation marks and brackets omitted). Instead, Schering records revenue when title and risk of loss pass to the wholesale purchaser. (Pet. App. 9a).

That said, Schering's revenue for its prescription pharmaceuticals business depends on the use of its products by retail consumers or patients, who must in turn obtain a prescription for the product from a physician. Thus, "a physician's prescription-writing practices and Schering's sales are related in a ripple effect up the supply chain, such that if physicians were to write fewer prescriptions or patients were to stop filling prescriptions written for Schering products, the demand for its products would reduce and Schering would experience lower sales to its wholesalers." (Pet. App. 9a) (citations and internal quotation marks omitted).

"To maintain or increase its market share, Schering promotes its products both through the work of PSRs and through direct-to-consumer advertising campaigns." (Pet. App. 10a). Respondents, like all Schering PSRs, were required to deliver a "core message" about a particular pharmaceutical product

to physicians "with the intent that this message will persuade physicians to prescribe products made by Schering rather than its competitors." (Pet. App. 11a-12a).

In addition to a base salary, PSRs earn "incentive payments based, roughly, on the number of prescriptions for Schering products written in the geographic area over which they have jurisdiction." (Pet. App. 13a). Direct links, however, are not, and indeed cannot, be made "between a PSR's work and a physician's prescription for a Schering product (and, thus, to resultant increases in Schering's market share), and Schering does not establish a 'one-to-one relationship' between them." (*Id.*, citations omitted). In many cases, PSRs "'work collaboratively' and in tandem with direct-to-consumer advertising campaigns, which makes specific attribution impossible." (*Id.*).

During "their visits with physicians Schering's PSRs do not enter into contracts with physicians over the price or quantity of Schering's products, obtain their orders for Schering's products, or get binding commitments from the physicians to purchase or prescribe Schering's products." (Pet. App. 17a).

D. The District Court's Ruling

The district court denied Schering's motion for summary judgment on its affirmative defense that respondents were properly classified as exempt from the FLSA as outside sales persons. (Pet. App. 5a-44a)

(*Kuzinski v. Schering*, 604 F. Supp.2d 385 (D. Conn. 2009)).

The court observed that exemptions to the FLSA's overtime protections must be "narrowly construed against the employers seeking to assert them," and then only if the employer establishes that an employee "plainly and unmistakably" fits within such an exemption. (Pet. App. 22a (citing *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392 (1960)).

The district court noted that, under the FLSA, the term "sale or sell" includes "any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition," 29 U.S.C. § 203(k), and also "include[s] the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property," 29 C.F.R. § 541.501(b). (Pet. App. 32a). Based on the nature of respondents' jobs, the district court readily concluded that "Schering's PSRs do not make, or engage in, any of these things. PSRs do not consummate or make any 'sales' of pharmaceuticals to the physicians they visit. PSRs do not 'exchange' with physicians for any drugs; they do not make any 'contract[s] to sell' drugs to physicians; they do not make any 'consignment for sale' with physicians; they do not make any 'shipment[s] for sale' to physicians; and they do not make any "other disposition" of drugs with physicians." (*Id.*).

The district court explained that "PSRs and physicians do not even have the capacity to consummate

sales," because they "are barred both by law" and by Schering "from entering into contracts for the prescription of their employer's products." (Pet. App. 33a).

The district court concluded that the "closest that Schering's PSRs come to consummating 'sales' is increasing the overall demand for its products, such that non-PSR Schering employees negotiate and commit to contracts with wholesalers – not the physicians to whom Schering's products are promoted." (Pet. App. 35a). "An employee does not consummate a 'sale' for purposes of the FLSA merely by 'lay[ing] the groundwork' for another employee to obtain a customer's commitment." (*Id.*) (citing *Clements v. Serco*, 530 F.3d 1224, 1229 (10th Cir. 2008)); 29 C.F.R. § 541.503(a) (even though promotional work can be considered exempt sales work, "promotional work that is incidental to sales made, or to be made, by someone else is not exempt outside sales work").

Indeed, the district court noted, "not only do the PSRs not consummate the sales, but the physicians with whom the PSRs visit are not Schering's customers." (Pet. App. 35a). Thus, insofar as "PSRs lay foundation or groundwork, it is to increase or maintain their employer's market share for the products they promote," but in "no more direct a manner" than "a pharmaceutical company's direct-to-consumer advertising, which raises demand for that company's products"; neither activity "constitutes 'sales' under the FLSA." (Pet. App. 35a-36a).

The district court reviewed the plain language of the FLSA and its mandated delimiting regulations, *see supra* at 3-6, and concluded "the outside sales exemption" does not apply to Schering's PSRs because they "do not make sales or obtain orders or contracts." (Pet. App. 27a).

E. The Second Circuit's Ruling

On interlocutory appeal, the court of appeals summarily affirmed the district court's denial of summary judgment and remanded the case for proceedings on other issues. (Pet. App. 1a-4a). It did so, "for the reasons stated in the district court's ruling and for the reasons stated in [its] opinion in *In re Novartis Wage Litig.*, [611 F.3d 141 (2d Cir. 2010) (Pet. App. 45a-78a)]." (Pet. App. 3a). Thus, the court of appeals fully adopted the district court's ruling which was made in 2009 based on the FLSA and its implementing regulations, but *before* the Secretary published her industry-specific interpretation of those regulations, as applied specifically to pharmaceutical representatives, in an *amicus* brief in the case heard in tandem with this one – *In re Novartis*.

While the court of appeals quite rightly accorded "controlling" deference, under *Auer v. Robbins*, 519 U.S. 452, 461 (1997), to the Secretary's interpretations of the regulations as set forth in an *amicus* brief in *In re Novartis*, Pet. App. 61a, the holding of the court of appeals was based on the reasoning of the district court which had interpreted the regulations

and found them plain and unambiguous even absent the Secretary's interpretation.

The court of appeals, in *In re Novartis*, noted that "Novartis sells its drugs to wholesalers; the wholesalers then sell them to pharmacies; and the pharmacies ultimately sell the drugs to patients who have prescriptions for them. The Reps promote the drugs to the physicians; the Reps do not speak to the wholesalers or to the pharmacies or to the patients." (Pet. App. 70a). The sales path for Novartis products is identical to that for Schering products. *See supra* at 6-8. The nature of the interactions between "Reps" and doctors is also the same for both Novartis and Schering. The doctors "neither buy pharmaceuticals from the Reps nor commit to buying anything from the Reps or from Novartis [or Schering]." (Pet. App. 70a). And, while the "physician is of course an essential step in the path that leads to the ultimate sale of a Novartis [or Schering] product to an end user; a patient cannot purchase the product from a pharmacy without a prescription, and it is the physician who must be persuaded that a particular Novartis [or Schering] drug may appropriately be prescribed for a particular patient." (*Id.*).

Moreover, as the court explained, the "type of 'commitment' the Reps seek and sometimes receive from physicians is not a commitment 'to buy' and is not even a binding commitment to prescribe." (*Id.* 71a). Indeed, there is "no way to know whether any physician [will] actually follow[ ] through on such a

commitment," as "a physician might answer affirmatively just to get the Rep out the door." (*Id.* 51a).

The court in *In re Novartis* thus held that where a pharmaceutical "employee promotes a pharmaceutical product to a physician but . . . cannot lawfully transfer ownership of any quantity of the drug in exchange for anything of value, cannot lawfully take an order for its purchase, and cannot lawfully even obtain from the physician a binding commitment to prescribe it," it is reasonable to conclude that an "employee has not in any sense, within the meaning of the statute or the regulations, made a sale." (Pet. App. 71a-72a).

REASONS FOR DENYING THE PETITION

I. THE COURT OF APPEALS DECISION IS NOT IN CONFLICT WITH OTHER COURTS OF APPEALS OR WITH DECISIONS OF THIS COURT

Petitioner does not contend that the decision of the court of appeals is in conflict with any decisions from other courts of appeals or decisions of this Court. Sup. Ct. R. 10. Nor could it. There are no such conflicts. Instead, petitioner contends that a writ of certiorari should be issued because the "Second Circuit erred." "A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." *Id.* It should not be granted here.

II. PETITIONER'S CONTENTION THAT "THE SECOND CIRCUIT ERRED IN ITS CONSTRUCTION OF THE OUTSIDE SALES EXEMPTION" IS WRONG

Petitioner argues that a writ of certiorari should issue because the Second Circuit's decision was error that has suddenly imposed "substantial and unexpected liabilities" on the pharmaceutical industry. Pet. at 2. There is no error. There has been no change.

A. There is no error. The decisions below contain a straightforward application of this Court's longstanding precedents and of the uniform precedents of the courts of appeals concerning the discrete and limited application of the FLSA's outside sales exemption.

For more than seventy years, the DOL and the courts have consistently interpreted the outside sales exemption narrowly, in a manner that has maintained a readily identifiable line between: (1) employees who work outside of an office and are engaged directly in consummating the sale of goods and services between their employers and consumers; and (2) those who are engaged generally in activities designed to promote, encourage and drive sales consummated by others. *See* 29 C.F.R. § 541.503(a)-(c).[4]

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[4] *See also Clements v. Serco, Inc.*, 530 F.3d 1224, 1229 (10th Cir. 2008) (Private recruiters who "sold" idea of joining the army to potential enlistees, but did not obtain binding commitments, were not outside salesmen; the enlistees signed up at U.S. Army

(Continued on following page)

This makes perfect sense. Absent the long-existing, plain and easily ascertainable line between actually closing a deal on one's own sales versus simply promoting an employer's goods or services, confusion would reign. Employers would not know which employees engaged in promotional, marketing, advertising and similar types of work outside a place of business and would be exempt from coverage by the FLSA. Moreover, an exemption that included all employees engaged in activities designed to increase demand for their employer's goods or services – like the one urged by petitioner – would swallow the rule. It would include all manner of marketing and promotion employees. Indeed, relatively few employees are engaged in activities that are not designed to increase demand for their employer's goods or services.

For example, under petitioner's understanding, employees distributing promotional literature or wearing sandwich boards on the sidewalk would be exempt from the FLSA as outside sales persons. They could be paid less than the minimum hourly wage and be denied overtime pay. No rational

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stations and thus, the recruiters merely promoted sales made by someone else); *Ackerman v. Coca-Cola Enterprises, Inc.*, 179 F.3d 1260 (10th Cir. 1999) (promotional work performed by delivery route drivers in support of their own sales is subject to outside sales exemption); *Wirtz v. Keystone Readers Service, Inc.*, 418 F.2d 249, 260 (5th Cir. 1969) ("To the extent that [Plaintiffs] are engaged in promotional activities designed to stimulate sales which will be made by someone else the work [is] non-exempt.").

interpretation of the FLSA could allow for such a result, and it has never been the law.

B. There has been no change. While Schering's petition is long on assertions that the decisions below and the Secretary's *amicus* brief in *In re Novartis*, "changed the definition of the exemption itself," Pet. at 2, or worked "a clear departure from the [Secretary's] past position," Pet. at 12, or constituted a "new and heightened requirement that a direct transaction be consummated between sales representative and customer," Pet. at 13, it is entirely lacking in any concrete support.

The undeniable truth is that, for over seventy years, consistent with the language of the FLSA, the DOL has held firm to the bright line it sensibly created in its first delimiting regulations in 1940. As explained in the 1940 Stein Report:

> A further group of persons for whom exemptions has been asked and who are admittedly not outside salesmen, in that they do not make actual sales, are sales promotion men and missionary men. These persons are engaged in paving the way for salesmen. . . . [I]t is clear that it would be an unwarrantable extension . . . to describe as a salesman anyone who does not in some sense make a sale. *Sales promotion and missionary men are persons who normally make no sales at all.*

Id. at 46-47 (emphasis supplied).

Sixty-four years later, in the most recent iteration of the regulations, the DOL explained that:

> The Department does not intend to change any of the essential elements required for the outside sales exemption. . . . An employer cannot meet this requirement unless it demonstrates objectively that the employee, in some sense, has made sales. *See* 1940 Stein Report at 46 (outside sales exemption does not apply to an employee "who does not *in some sense* make a sale") (emphasis added). Extending the outside sales exemption to include all promotion work, whether or not connected to an employee's own sales, would contradict this primary duty test. *See* 1940 Stein Report at 46 (outside sales exemption does not extend to employees "engaged in paving the way for salesmen, assisting retailers, and establishing sales displays, and so forth").

Pet. App. 104a; *see also* 69 Fed. Reg. 22142.

Notwithstanding the Secretary's decades long, unbroken and unambiguous regulatory line drawing, petitioner argues that "[b]efore DOL's appearance in the court below, the outside sales exemption did not impose a requirement that sales employees consummate direct transactions with their customers." Pet. 29. The excerpts from the regulatory interpretations in 1940 and 2004 cited above conclusively refute this claim.

When the DOL regulations were updated in 2004, the substance of the outside sales exemption was expressly left unchanged.[5] Indeed, for many years before the non-substantive update in 2004, the DOL's regulation concerning the important line between actual sales and promotional work provided an illustration that undoubtedly put the pharmaceutical industry on notice that sales representatives could not possibly be exempt from the FLSA.

The example explained that "a manufacturer's representative who visits retailers accompanied by a salesman for a distributor (or 'jobber')" was not exempt as an outside sales person, if "the manufacturer's representative does preliminary work ('which may include . . . talking to the retailer for the purpose of getting him to place the order for the product'), but the distributor's salesman actually takes the order after the preliminary work is done, . . . *See* 29 C.F.R. § 541.505(c)(2)." *Ackerman v. Coca-Cola Enterprises, Inc.*, 179 F.3d 1260, 1265 (10th Cir. 1999).

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[5] As the DOL explained: "[T]he Department does not intend to change any of the essential elements required for the outside sales exemption, including the requirement that the outside sales employee's primary duty must be to make sales or to obtain orders or contracts for services." Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22121 (2004).

Like the 1940 Stein Report,[6] former 29 C.F.R. § 541.505(c)(2) could not have been more clear. When a manufacturer of tangible products, like Schering, has a business model where it sells only to wholesale distributors or "jobbers" (or even retailers, as Schering occasionally does) – but never to actual consumers of Schering's products – the fact that the manufacturer's representatives, here PSRs like respondents, engage in activities designed to encourage someone to place an order with the wholesaler (or even the retail pharmacy) does not qualify that person as an exempt outside sales person.

This is so, explained the DOL in the illustration, because the actual sale is not made by the employer-manufacturer to the person interacting with the employee, but rather by an independent wholesaler (or pharmacy) that actually sells the employer-manufacturer's product to the retailer (or the end user or consumer), after the work to drive demand for the sale has been completed by the employee.

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[6] The exclusion from exemption of sales promotion employees who attempt to influence the buying habits of those who do not purchase directly from their employers, but rather from middlemen, distributors, wholesalers or "jobbers," dates back to the inception of the FLSA. "Frequently the sales promotion man deals with retailers who are not customers of his own employer but of his employer's customer, the jobber." 1940 Stein Report at 46. Such, "sales promotion men" do "not make actual sales," and thus "it would be an unwarrantable extension . . . to describe as a salesman anyone who does not in some sense make a sale." *Id.*

No one could have read this illustrative example and concluded that Schering's PSRs were exempt from the FLSA as outside sales persons. After all, PSRs promote Schering products to doctors in an effort to persuade them to prescribe Schering products to patients. If PSRs are successful and a doctor prescribes a Schering product as a result of their efforts, the patient may or may not fill the prescription at a retail pharmacy. If the prescription is filled, it may influence the independent pharmacy to buy more Schering products from the independent wholesaler (or possibly directly from Schering). And, if the independent pharmacy buys more Schering products from the independent wholesaler, it may influence the independent wholesaler to buy more products from Schering. As explained above, Schering does sell its products, but not directly to consumers.

PSRs are no more exempt as outside sales representatives than a person employed by the Kellogg Company to play "Tony the Tiger" on visits to supermarkets promoting Kellogg's Frosted Flakes. Tony the Tiger may increase sales by influencing children to beg their parents to purchase Frosted Flakes. And, that may, in turn, mean that supermarkets purchase more Frosted Flakes from wholesalers or "jobbers," but that does not make the person playing the mascot exempt from the FLSA's minimum wage and mandatory overtime requirements as an outside sales person.

III. THERE IS NOTHING UNUSUAL ABOUT THE SECOND CIRCUIT'S DECISION TO DEFER, UNDER *AUER*, TO THE SECRETARY'S CONSIDERED INTERPRETATION OF HER OWN REGULATIONS

Petitioner argues that this Court's "guidance" is needed to "clarify" the "scope" of deference owed the DOL's interpretation of its own regulations under this Court's unanimous decision in *Auer v. Robbins*, 519 U.S. 452 (1997). Pet. 14. Petitioner does not explain, however, just what it is about *Auer* that warrants "clarification."

This Court's teaching in *Auer* is straightforward. Insofar as an agency interpretation of its own regulations is "not plainly erroneous or inconsistent with the regulation," the agency's interpretation should be granted controlling deference. 519 U.S. at 461 (internal citations omitted). In *Auer*, as in *In re Novartis*, the DOL's interpretation was provided in the form of an *amicus* brief. More recently, and consistent with the holding in *Auer*, this Court gave controlling deference to a DOL Advisory Memorandum issued during pending litigation. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 159, 171 (2007).

The "scope" of *Auer* deference is plain and unambiguous. Indeed, courts of appeals throughout the country have handily applied *Auer's* holding. *See, e.g., Sec'y of Labor v. Beverly Healthcare-Hillview*, 541 F.3d 193, 200 (3d Cir. 2008) (holding that the Secretary of Labor's interpretation of an OSHA regulation was reasonable and therefore

entitled to *Auer* deference because it did not impermissibly strain the plain language of the regulation and the interpretation was consistent with the purpose of the regulation); *IntraComm, Inc. v. Bajaj*, 492 F.3d 285, 295-96 (4th Cir. 2007) (deferring to the DOL's interpretation of its regulation in an amicus brief); *Rucker v. Lee Holding Co.*, 471 F.3d 6, 12 (1st Cir. 2006) (granting controlling weight to the DOL's interpretation of its regulation where the DOL's position was consistently held and consonant with the language of the regulation); *Belt v. Emcare, Inc.*, 444 F.3d 403, 415-16 (5th Cir. 2006); *Archuleta v. Wal-Mart Stores, Inc. (In re Wal-Mart, Inc.)*, 395 F.3d 1177, 1185 (10th Cir. 2005) ("We see no reason to accord less deference to [DOL] Wage & Hour opinion letters than the Supreme Court gave to the position of the DOL set forth in an amicus brief to the Court, . . . particularly when, as shown below, the letters reflect a consistent view over an extended period of time").

Insofar as Schering takes a stab at explaining what it was about the *In re Novartis* court's application of *Auer* deference that warrants certiorari, it says that this Court's guidance is "needed to clarify the extent to which *Auer* deference" applies to a "change in agency interpretation" announced "for the first time in an *amicus* brief." Pet. 15. This argument is deeply flawed as a matter of both fact and law.

It is factually wrong because, as explained *supra* at 16-20, the DOL's interpretation of its outside sales regulations does not depart in any way from the plain

language of the regulations themselves or past DOL interpretations of those regulations.

It is legally wrong because it assumes that "guidance" is needed in circumstances – not presented here – where an agency's interpretation of its regulations is inconsistent with the regulations themselves or prior agency interpretations. But, *Auer*, of course, addresses that exact circumstance. *Auer* teaches that an agency interpretation, whether in an *amicus* brief or something else, is *not* to be given controlling deference precisely because it is "inconsistent." 519 U.S. at 461.

For reasons canvassed above, the conditions for *Auer* deference are present here. Indeed, the district court rejected petitioner's interpretation without the benefit of the Secretary's deference-deserving interpretation, and the Second Circuit expressly endorsed the district court's independent interpretation. At most, petitioner's quarrel is not with *Auer*, but rather with the court of appeals' application of it here. Needless to say, a "petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." Sup. Ct. R. 10.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

SCHERING CORPORATION,

Petitioner,

v.

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, AND SHAWN JONES, ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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SUPPLEMENTAL BRIEF FOR PETITIONER

Schering Corporation's petition for writ of certiorari raises two questions for the Court's review: (1) whether *Auer* deference should be extended to the Department of Labor's unsolicited *amicus* brief when that interpretation causes unfair surprise and imposes substantial liability on the pharmaceutical industry; and (2) whether the Second Circuit committed error in imposing new and technical requirements on the outside sales exemption. On February 14, 2011, the Ninth Circuit's answers to those questions created a circuit split both as to the deference owed to DOL and the exempt status of pharmaceutical salespersons. Pursuant to Supreme Court Rule 15.8, therefore, Petitioner Schering submits this supplemental brief.

A. A circuit split now exists as to important questions of federal law presented by Schering's petition.

In one of the many collective action lawsuits filed against virtually all pharmaceutical companies since 2006, Schering moved for summary judgment on the ground that its employees were properly classified as outside salespersons. The trial court denied Schering's motion, but, because other courts had ruled differently on the same issue, granted Schering's motion for interlocutory appeal.

Schering's appeal was heard in tandem with *In re Novartis Wage & Hour Litigation*, 611 F.3d 141 (2d Cir. 2010) (App. C at 45a) ("*Novartis*"). The Department of Labor appeared *sua sponte* in *Novartis* on behalf of the plaintiffs (App. M at 110a),

and, for the first time, took the position that pharmaceutical sales representatives are not outside sales or administrative employees. The Second Circuit afforded controlling deference to DOL's interpretation in *Novartis* under *Auer v. Robbins*, 519 U.S. 452 (1997), and found that Schering's pharmaceutical sales representatives do not make "sales" as that term was interpreted and explained by DOL's *amicus* brief.

After the ruling in *Novartis*, plaintiffs' counsel in similar cases asked other courts to afford the same deference to DOL's *amicus* brief. The District Court of Arizona rejected that argument in *Christopher v. SmithKline Beecham Corporation* and ruled that DOL's interpretation was inconsistent with both the statutory language and its prior pronouncements. 2010 WL 396300, at *2 (D. Ariz. Feb. 1, 2010).

As in *Novartis,* upon plaintiffs' appeal of the order granting judgment to defendant, DOL filed an unsolicited *amicus* brief before the Ninth Circuit that, among other things, argued that the plaintiffs did not make sales because they did not engage in a consummated transaction with physicians.

B. A circuit split exists as to the deference owed to DOL's *Amicus* Brief.

After examining the FLSA and the outside sales exemption in detail, the Ninth Circuit concluded that no deference was owed to DOL's new interpretation expressed in its *amicus* brief:

> Although the *Novartis* court held that [the] Secretary's interpretation was owed *Auer* deference, 611 F.3d at 153, our review of the

> relevant authorities leads us to a different conclusion. We conclude that we owe no deference to the Secretary's current interpretations of the regulations, and, in any event, we respectfully disagree with that interpretation.

Christopher v. SmithKlineBeecham Corp., No. 10-15257, Slip Op. at 2347 (9th Cir. Feb. 14, 2011).

In reaching its decision, the court carefully explained the basis for its disagreement with *Novartis*. Relying upon the guidance stated in *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006) the *Christopher* court concluded that the existing regulations defining the term "sale" merely parroted the language provided by Congress. Slip Op. at 2351-53. "A definition dependent almost entirely on Congress's seventy-two-year old statutory language is not an example of the DOL employing its 'expertise' to elucidate meaning to which we owe *Auer* deference." *Id.* at 2351. Rather than interpret a regulation's ambiguous language as required for *Auer* deference, the Secretary "used her appearance as *amicus* to draft a new interpretation of the FLSA's language." *Id.* at 2351-53. The Ninth Circuit held, therefore, "that we need not give 'controlling' deference to the Secretary's interpretation in this matter." *Id.* at 2353-54. To do otherwise would "unduly expand *Auer*'s applicability to interpretations of status expressed for the first time in case-by-case *amicus* filings." *Id.* at 2353.

The Ninth Circuit's conclusion is precisely the opposite of that reached by the Second Circuit in *Novartis*, where the court rejected the argument that no deference was owed to DOL's brief because the

regulation at issue paraphrased statutory language. Instead, the *Novartis* court looked beyond the regulation defining the term at issue – "sale" – and found that DOL's regulations "do far more than merely parrot the language of the FLSA." 611 F.3d at 153.[1]

The circuit split that now exists as to the deference to be afforded an agency's interpretation when expressed in an *amicus* brief under circumstances similar to those here amplifies the need for this Court's guidance in clarifying the limits of *Auer* deference and the interplay between *Auer* and *Gonzales*. *See* Pet. at 12-21; Reply at 3-4.

The *Christopher* court, however, did not stop there, for "even if *Auer* applied, deference is not warranted because the Secretary's position is both plainly erroneous and inconsistent with her own regulations and practices." Slip Op. at 2354. With that ruling, a split between the two courts of appeals has also arisen as to the second of Schering's questions presented for review.

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[1] Also of clear concern to the Ninth Circuit was the unfair surprise caused by DOL's shift in thinking after 70 years of "acquiescence in the sales practices of the drug industry." Slip Op. at 2361. As the court noted, "[u]ntil the Secretary's appearance in *Novartis*, the DOL did not challenge the conventional wisdom that detailing is the functional equivalent of selling pharmaceutical products." *Id.* The *Novartis* court made no mention of the change in position being made by DOL in its new interpretation of the exemption.

C. A circuit split exists as to the interpretation and application of the outside sales exemption.

In its analysis of the outside sales exemption, the *Christopher* court explored the practical realities of the pharmaceutical industry and the manner in which sales may lawfully be made and found that those realities were integral to an analysis of the exemption:

> In this industry, the "sale" is the exchange of non-binding commitments between the PSR and physician at the end of a successful call. Through such commitments, the manufacturer will provide an effective product and the doctor will appropriately prescribe; for all practical purposes, this is a sale. Because pharmaceutical manufacturers appreciate who the 'real' buyer is, they have structured their 90,000-person sales force and their marketing tactics to accommodate this unique environment.

Slip Op. at 2355. Employing a common-sense understanding of what it means to make sales, *id.* at 2357, the court found that the primary duty of a pharmaceutical sales representative is to obtain "a commitment to purchase (prescribe) something." *Id.* at 2359.

The Ninth Circuit rendered its decision while fully acknowledging the Second Circuit's conclusion in *Novartis* (and ultimately in Schering's appeal) that non-binding commitments to prescribe between pharmaceutical sales representatives and physicians do not satisfy the exemption. *Id.* at 2350-51. These

irreconcilable conclusions as to the definition and interpretation of the outside sales exemption raise serious and substantial conflicts for all businesses.

In the Ninth Circuit, for example, it is enough that an employee "in some sense" makes a sale to properly classify that employee as an outside salesperson. In the Second Circuit, the employee must instead engage in a direct exchange of a good for consideration or must obtain a legally-binding commitment directly from the buyer to be exempt from the FLSA's overtime requirements.

The practical realities of the manner in which a business operates should be considered in determining whether an exemption applies in the Ninth Circuit. In the Second Circuit, a commonsensical approach is rejected and practical realities of the industry in which the employee works are ignored.

The phrase "other disposition" has two different meanings depending on where the sales exemption is applied. In the Ninth Circuit, it does not require a transfer of title. In the Second Circuit, the phrase is construed rigidly to require such a transfer.

DOL's "acquiescence in the sales practices of the drug industry for over seventy years" matters in the Ninth Circuit. Slip Op. at 2361. In the Second Circuit, DOL's decades-long silence as to the exempt status of pharmaceutical sales representatives is of no consequence.

In the Ninth Circuit, employees who are hired for their sales experience, trained on sales methods, engaged in encouraging physicians to prescribe their products, and compensated in part by commissions tied to sales are salespersons. Slip Op. at 2355. In

the Second Circuit, the sales nature of the position is not part of the analysis of the exemption.

CONCLUSION

For the foregoing reasons and the reasons stated in the Petition, Schering Corporation respectfully requests that the Court grant its Petition for a Writ of Certiorari.

Respectfully submitted,

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February 15, 2011

APPENDIX

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Michael Shane Christopher;
Frank Buchanan, individually and
On behalf of all others similarly situated,
Plaintiffs-Appellants,

v.

SmithKline Beecham Corporation,
DBA GlaxoSmithKline,
Defendant-Appellee.

No. 10-15257
D.C. No. 2:08-cv-01498-FJM

OPINION
Appeal from the United States District Court
For the District of Arizona
Frederick J. Martone, District Judge,
Presiding

Argued and Submitted
November 3, 2010 – Pasadena, California

Filed February 14, 2011
Before Mary M. Schroeder, Richard C. Tallman, and
Milan D. Smith, Jr., Circuit Judges.
Opinion by Judge Milan D. Smith, Jr.

OPINION

M. SMITH, Circuit Judge:

***2334** Plaintiffs Appellants Michael Christopher and Frank Buchanan appeal the judgment of the district court that they are not entitled to overtime pay under the Fair Labor Standards Act of 1938 (FLSA), 29 U.S.C. §§ 201 *et seq.* Plaintiffs were employed as Pharmaceutical Sales Representatives ***2335** (PSRs) for Defendant-Appellee SmithKline Beecham Corporation d/b/a GlaxoSmithKline (Glaxo). Glaxo classified Plaintiffs as "outside salesmen"—a legal designation that exempts an employee from the FLSA's overtime-pay requirement. Plaintiffs' suit challenges Glaxo's classification and seeks back pay. The district court granted summary judgment to Glaxo. We affirm.

FACTUAL AND PROCEDURAL BACKGROUND

I. Pharmaceutical Sales Representatives

Glaxo is in the business of developing, producing, marketing, and selling pharmaceutical products. Christopher and Buchanan began working as PSRs for Glaxo in 2003. Glaxo terminated Christopher in May 2007. Buchanan's career at Glaxo ended when he accepted a PSR position at another pharmaceutical company. Since the enactment of the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, federal law has, to varying degrees, regulated and influenced the sale of pharmaceuticals.[1] In 1938, the Federal Food, Drug,

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[1] *Cf.* Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug*

and Cosmetic Act, Pub. L. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301 *et seq.*), clothed the Food and Drug Administration with broad regulatory authority over, *inter alia*, drug manufacturers.[2] The Durham-Humphrey Amendment of 1951 established the first comprehensive scheme governing the sale of prescription pharmaceuticals to the public. *See* Pub. L. No. 82-215, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353(b)). Importantly, for our purposes, Durham-Humphrey formalized the now well-established dis-***2336**tinction between prescription and over-the-counter drugs.[3] The Controlled Substances Act of 1970, Pub. L. 91-513, 84 Stat. 1260, continues the prescription/non-prescription dichotomy, and prohibits dispensing the former without the authorization of a "practitioner, other than a pharmacist, to an ultimate user." 21 U.S.C. § 829(b)-(d). Currently, all pharmaceuticals requiring a physician's prescription are branded "Rx only." 21 U.S.C. § 353(b)(4)(A).

We analyze this case within the framework of how Glaxo sells its "Rx only" products to an "ultimate user." A key, undisputed fact underlying our analysis is that the ultimate user—the patient—cannot purchase a prescription drug without first obtaining a physician's authorization.

Advertising Regulation, 57 Food & Drug L.J. 423, 424-27 (2002).

[2] *See* Palumbo & Mullins, *supra*, at 425 & n.17.

[3] *See* Palumbo & Mullins, *supra*, at 426.

Because Glaxo is proscribed from selling Rx-only products directly to the public, it sells its prescription pharmaceuticals to distributors or retail pharmacies, which then dispense those products to the ultimate user, as authorized by a licensed physician's prescription. In this restrictive sales environment, Glaxo employs PSRs to make "calls" on physicians to encourage them to prescribe Glaxo products. On calls, PSRs typically present physicians with a variety of information about Glaxo products, provide product samples, and attempt to convince the physicians to prescribe Glaxo products, when medically appropriate, over competitor products. PSRs also try to build business relationships with physicians, respond to their concerns, and recruit them to attend Glaxo-organized dinners and conventions. Each PSR is responsible for a particular "drug bag" of medications he or she tries to induce physicians to prescribe. As perceived by the Plaintiffs, the primary duty of a PSR is to communicate features and benefits of Glaxo products to physicians. In Buchanan's words, he tried to "convince prescribers that the benefits of [Glaxo's] products warranted them prescribing that product to the appropriate patient."

***2337** PSRs usually work outside of a Glaxo office and spend much of their time traveling to the offices of, and working with, physicians within their assigned geographic territories. Plaintiffs visited between eight and ten physicians each day, usually between the hours of 8:30 a.m. and 5:00 p.m. Plaintiffs claim that they worked between ten and twenty hours each week outside of normal business hours, for which they received no overtime wages. When not making calls on physicians, Plaintiffs

studied Glaxo products and relevant disease states, prepared new presentation modules, answered phone calls, checked email, generated reports, and attended events on evenings and weekends.

Before a PSR makes his or her daily calls, Glaxo provides him or her with detailed reports about the physicians he or she will visit. These reports include information about a physician's prescribing habits and drug preferences, the market volume of Glaxo products prescribed by the physician versus the volume of competitor products, and the volume of prescriptions filled in a particular region. Glaxo also provides each PSR with a budget to use for speaker programs and to engage socially with physicians.

Glaxo prepares and provides information about its products—called "Core Messages"—for PSRs to present to physicians during calls. Core Messages include information about product benefits and risks, dosage instructions, and the types of patients for whom Glaxo recommends each product. Glaxo expects PSRs to use the Core Messages and then "[d]evelop and deliver informative sales presentations based on customer needs."

PSRs do not carry any prescriptions with them for direct sale; rather, Glaxo provides PSRs with small amounts of sample products to distribute to physicians. PSRs do not contact patients or market anything to them. To the contrary, in compliance with federal law, PSRs cannot sell the samples, take ***2338** orders for any medication, or negotiate drug prices or contracts with either physicians or patients.

Glaxo recruits applicants who have prior sales experience for its PSR positions. When Glaxo hires

new PSRs, it provides them with more than one month of training that focuses on making presentations, learning about Glaxo products, and building interpersonal skills. PSRs are taught how to ask for a commitment from a physician to prescribe Glaxo products if the physician believes the medication is appropriate.

Since 2001, Glaxo has instructed PSRs on various methods of completing a call. When Plaintiffs were hired, they received training in Glaxo's "Assertive Selling Always Professional (ASAP)" model. They were also trained to follow Glaxo's "Winning Practices" program. ASAP and Winning Practices are similarly structured and emphasize that a PSR should: (1) analyze and understand what is happening in an assigned region; (2) work with the team to drive results; (3) master professional knowledge to understand clinical management of patients; (4) prepare for calls; (5) "Sell Through Customer-Focused Dialogue"; (6) obtain the strongest commitment possible from a healthcare professional at the end of the call; and (7) provide added value to the customer relationship.

In 2004, Glaxo started a new program called "When? Why? How?" which distilled the old model into three questions PSRs should use to bond the targeted physician to the Glaxo brand: "(1) When should I use this product? (2) Why should I use this product? (3) How should I use this product?" PSRs strive to ensure that their targeted physicians have the answers to all three questions before PSRs leave the physicians' offices.

Plaintiffs received two types of pay—salary and incentive-based compensation. Incentive-based

compensation is paid if Glaxo's market share for a particular product increases in a ***2339** PSR's territory, sales volume for a product increases, sales revenue increases, or the dose volume increases. Glaxo aims to have a PSR's total compensation be approximately 75% salary and 25% incentive compensation.[4] However, the dollar value of incentive-based compensation is uncapped. The process of providing information to physicians is referred to within the pharmaceutical industry as "detailing," and PSRs have traditionally been known by the moniker "detail men" or "detailers." Plaintiffs' job functions during their tenures at Glaxo varied little from those of their predecessors of fifty or sixty years ago.[5] Moreover, there is homogeneity ***2340**

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[4] In 2004, Christopher received $72,576 gross pay, of which $29,993 was incentive compensation (41% of gross); in 2005, he received $67,243, of which $21,231 was incentive (32% of gross); and in 2006, he received $77,552, of which $28,249 was incentive (37% of gross). In 2004, Buchanan received $70,740 gross pay, of which $19,232 was incentive compensation (27% of gross); in 2005, he received $74,358, of which $27,743 was incentive (32% of gross); in 2006, he received $84,932, of which $32,519 was incentive (38% of gross); and in 2007, he received $75,776, of which $19,957 was incentive (26% of gross).

[5] *See* Thomas L. Hafemeister, et ano., *Beware Those Bearing Gifts: Physician's Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 U. Kan. L. Rev. 491, 493-94 (2009) ("Detailing is the term used to denote the practice of pharmaceutical representatives visiting the offices of physicians or otherwise contacting physicians to promote their company's drugs and/or medical devices."). The pharmaceutical-representative/detailist position has deep roots in the industry, dating back until at least the 1930s. *See* Lars Noah, *Death of a*

within the industry—PSRs carry out essentially the same business functions regardless of which drug manufacturers they represent.[6] The pharmaceutical

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Salesman: To What Extent Can the FDA Regulate the Promotional Statements of Pharmaceutical Sales Representatives, 47 Food & Drug L.J. 309, 311 (1992) ("During the 1930s, . . . [m]arketing efforts by salesmen therefore focused almost exclusively on retail pharmacies."). Indeed, we trace the first mention of detail men in the federal case reports to 1940. *See United States v. Fifty-Nine Tubes, More or Less, of Lutein Tablets*, 32 F. Supp. 958, 960 (S.D.N.Y. 1940) (describing how "detail men or salesmen" interacted with physicians); *see also Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (referring to "Pfizer's detail men" providing drug information to a physician); *N. Cal. Pharm. Ass'n v. United States*, 306 F.2d 379, 386 (9th Cir. 1962) ("'Detail men,' or local sales representatives of the out-of-state manufacturers are constantly at work in northern California acquainting physicians and pharmacists with new drugs, stimulating interest generally in the firm's products, and urging physicians to prescribe, and pharmacists to order, the manufacturer's goods."); *Schering Corp. v. Sun Ray Drug Co.*, 320 F.2d 72, 74 (3d Cir. 1963) (explaining company's advertising included "efforts on the part of its detail men (who are salesmen)"); *Hoffmann-La Roche, Inc. v. Schwegmann Bros. Giant Super Mkts.*, 122 F. Supp. 781, 783 (E.D. La. 1954) ("[Detail men] regularly call upon physicians...").

[6] *See e.g.*, *IMS Health, Inc. v. Mills*, 616 F.3d 7, 14 (1st Cir. 2010) ("Detailing is a massive and expensive undertaking for pharmaceutical manufacturers, which spend billions of dollars a year to have some 90,000 pharmaceutical sales representatives make weekly or monthly one-on-one visits to prescribers nationwide."); *Pfizer, Inc. v. Astra Pharm. Prods., Inc.*, 858 F. Supp. 1305, 1314 (S.D.N.Y. 1994) ("It is not

industry self-regulates PSRs and their contacts with physicians by way of a voluntary industry-wide code of conduct—the Pharmaceutical Research and Manufacturers of America (PhRMA) Code. The PhRMA Code does not speak of selling, but, rather, provides that "[i]nteractions [with health care professionals] should be focused on informing [them] about products, providing scientific and educational information, and supporting medical research and education." The PhRMA Code refers to PSRs as "industry representatives" and states that "[i]nformational presentations and discussions by industry representatives speaking on behalf of a company provide valuable scientific and educational benefits." The PhRMA Code also regulates the provision of meals and gifts to physicians and professes an industry commitment to independent medical decisionmaking. ***2341**

II. Proceedings in the District Court

This litigation commenced in August 2008, when Plaintiffs filed the Complaint challenging Glaxo's practice of requiring overtime work without paying additional compensation as a violation of 29 U.S.C. §§ 207(a)(1), 216(b). The parties cross-moved for summary judgment, and Plaintiffs moved to certify a conditional class. Glaxo contended that Plaintiffs were exempt under the "outside salesman"

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disputed that the parties' marketing efforts are conducted in substantially similar ways through (a) advertising in medical journals, (b) mailings sent to doctors, and (c) the use of large forces of 'detail men' who solicit doctors at the latter's offices and discuss their products directly with the doctors.").

provision in FLSA or, alternatively, under the "administrative" exemption. 29 U.S.C. § 213(a)(1).

In granting Glaxo's motion for summary judgment, the district court addressed only the outside sales exemption and held that PSRs "unmistakably fit within the terms and spirit of the exemption." *Christopher v. SmithKlein Beecham Corp.*, No. 08 Civ. 1498 (FJM), 2009 WL 4051075, at *5 (D. Ariz. Nov. 20, 2009). The court observed that PSRs "are not hourly workers, but instead earn salaries well above minimum wage —up to $100,000 a year," and that they receive bonuses in lieu of overtime as "an incentive to increase their efforts." *Id.* The district court continued, "A PSR's ultimate goal is to close an encounter with a physician by obtaining a nonbinding commitment from the physician to prescribe the PSR's assigned product. In this highly regulated industry, that is the most a PSR can achieve." *Id.*

Thereafter, Plaintiffs moved to alter or amend the judgment based on the district court's failure to consider an *amicus* brief filed by the Secretary (Secretary) of the Department of Labor (DOL) in a FLSA appeal then pending before the United States Court of Appeals for the Second Circuit, *In re Novartis Wage & Hour Litig.*, 611 F.3d 141 (2d Cir. 2010). The district court rejected Plaintiffs' argument that the DOL brief was entitled to deference under either *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or *Auer v. Robbins*, 519 U.S. 452 (1997), and noted that the DOL's brief recapitulated the points argued at summary judg-***2342** ment. Finding the DOL's "current interpretation inconsistent with the

statutory language and its prior pronouncements, [and] [ ] also def[ying] common sense," the district court denied the motion to amend the judgment. Plaintiffs appeal.

JURISDICTION AND STANDARD OF REVIEW

We have jurisdiction under 28 U.S.C. § 1291.

We review a district court's interpretation of the FLSA and its grant of summary judgment de novo. *Gieg v. DDR, Inc.*, 407 F.3d 1038, 1044-45 (9th Cir. 2005); *see also Dent v. Cox Commc'ns Las Vegas, Inc.*, 502 F.3d 1141, 1143 (9th Cir. 2007). Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

DISCUSSION

I. The FLSA Outside Sales Exemption

The FLSA imposes minimum labor standards on employers to promote "the health, efficiency, and general well-being of workers." 29 U.S.C. § 202(a); *Nigg v. U.S. Postal Serv.*, 555 F.3d 781, 784 (9th Cir. 2009). The FLSA was "enacted because Congress found that the existence 'in industries engaged in commerce or in the production of goods for commerce' of labor conditions detrimental to maintaining minimum standards of living necessary for health, efficiency and general well-being of workers perpetuates substandard conditions among workers, burdens commerce, constitutes an unfair method of competition in commerce, leads to labor disputes,

and interferes with the orderly and fair marketing of goods." *Hale v. Arizona*, 993 F.2d 1387, 1396 (9th Cir. 1993) ***2343** (en banc) (quoting 29 U.S.C. § 202(a)) (emphasis added); *see also Nigg*, 555 F.3d at 784.

[1] To meet those goals and expand employment opportunities across the economy, the FLSA includes a baseline "overtime payment requirement" that employers must pay employees "a rate not less than one and one-half times the regular rate at which he is employed" for hours worked in excess of forty per week. 29 U.S.C. § 207(a)(1). There are numerous exceptions to this general rule. *See* 29 U.S.C. § 213. These exemptions to the overtime-pay requirement vary widely from "white-collar" executive, administrative, and professional exemptions to those for babysitters. 29 U.S.C. § 213(a)(1), (15). Relevant here is one part of the "white-collar" exemption for persons employed "in the capacity of outside salesman." 29 U.S.C. § 213(a)(1); *Vinole v. Countrywide Home Loans, Inc.*, 571 F.3d 935, 946 (9th Cir. 2009). The white-collar exemption removes from the overtime pay requirement:

> any employee employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary [of Labor]). . . .

29 U.S.C. § 213(a)(1) (emphasis added).

As the statute indicates, a proper interpretation of the FLSA is necessarily guided by the regulations issued by the Secretary of Labor—"[t]he FLSA grants

the Secretary broad authority to 'define and delimit' the scope of the exemption for executive, administrative, and professional employees." *Auer*, 519 U.S. at 456 (alterations and citation omitted). Congress did not define the term "outside salesman" or the other white-collar exemptions in the FLSA. Rather, "[p]ursuant to Congress's specific grant of rulemaking authority, the [DOL] has issued implementing regulations, at 29 C.F.R. Part 541 ***2344** [(Part 541)], defining the scope of the section 13(a)(1) exemptions." *See* Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 Fed. Reg. 22,122, 22,124 (Apr. 23, 2004). In 2004, the DOL's Wage and Hour Division promulgated supplemental rules concerning the outside sales and administrative exemptions (the 2004 Rule). Among other things, the 2004 Rule explained that "the major substantive provisions of the Part 541 regulations have remained virtually unchanged for 50 years." 69 Fed. Reg. at 22,124.

[2] The Secretary defines an "outside salesman" as any employee:

> (1) Whose primary duty is: (i) making sales within the meaning of section 3(k) of the Act; or (ii) obtaining orders or contracts for services or for the use of facilities for which a consideration will be paid by the client or customer; and
>
> (2) Who is primarily and regularly engaged away from the employer's place or places of business in performing such primary duty.

29 C.F.R. § 541.500(a). An employee's "primary duty" is "the principal, main, major, or most important duty that the employee performs." 29 C.F.R. § 541.700. The outside sales regulation provides:

> In determining the primary duty of an outside sales employee, work performed incidental to and in conjunction with the employee's own outside sales or solicitations, including incidental deliveries and collections, shall be regarded as exempt outside sales work. Other work that furthers the employee's sales efforts also shall be regarded as exempt work including, for example, writing sales reports, updating or ***2345** revising the employee's sales or display catalogue, planning itineraries and attending sales conferences.

29 C.F.R. § 541.500(b).

The Secretary's outside sales regulation references Section 3(k) of the Act. 29 C.F.R. § 541.500(a). Section 3(k) provides that " '[s]ale' or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k). The Secretary's regulations provide:

> Sales within the meaning of section 3(k) of the Act include the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property. Section 3(k) of the Act states that "sale" or "sell" includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition.

29 C.F.R. § 541.501(b).

In the regulations, the Secretary draws a distinction between sales work and promoting:

> Promotion work is one type of activity often performed by persons who make sales, which may or may not be exempt outside sales work, depending upon the circumstances under which it is performed. Promotional work that is actually performed incidental to and in conjunction with an employee's own outside sales or solicitations is exempt work. On the other hand, promotional work that is incidental to sales made, or to be made, by someone else is not exempt outside sales work.

29 C.F.R. § 541.503(a). To illustrate the concept of promoting sales, as opposed to selling, the Secretary's regulations pro-*2346vides two examples—a manufacturer's representative and a company representative who visits chain stores:

> (b) A manufacturer's representative, for example, may perform various types of promotional activities such as putting up displays and posters, removing damaged or spoiled stock from the merchant's shelves or rearranging the merchandise. . . . Promotion activities directed toward consummation of the employee's own sales are exempt. Promotional activities designed to stimulate sales that will be made by someone else are not exempt outside sales work. . . .
>
> (c) Another example is a company representative who visits chain stores,

> arranges the merchandise on shelves, replenishes stock by replacing old with new merchandise, sets up displays and consults with the store manager when inventory runs low, but does not obtain a commitment for additional purchases. The arrangement of merchandise on the shelves or the replenishing of stock is not exempt work unless it is incidental to and in conjunction with the employee's own outside sales. Because the employee in this instance does not consummate the sale nor direct efforts toward the consummation of a sale, the work is not exempt outside sales work.

29 C.F.R. § 541.503(b)-(c).

In a FLSA overtime-wage case, the question of how an employee spends his or her workday is one of fact, while the question of whether his or her activities exclude him or her from the overtime-pay requirement is one of law. *See Icicle Seafoods v. Worthington*, 475 U.S. 709, 714 (1986); *Bratt v. Cnty. of Los Angeles*, 912 F.2d 1066, 1068 (9th Cir. 1990). Although the outside sales exemption is more than seven decades old, our encounters with the exemption are few and lim-***2347**ited to the class-certification context. *See In re Wells Fargo Home Mortg. Overtime Pay Litig.*, 571 F.3d 953 (9th Cir. 2009); *Vinole*, 571 F.3d at 939, 945. Thus, whether a PSR's job duties make him or her an outside salesperson is a question of first impression for our court.

We construe the outside sales exemption consistent with other Section 13(a) exemptions under the FLSA. The employer always has the burden of

showing the exemption applies to its employee. *Bratt*, 912 F.2d at 1069; *see also Nigg*, 555 F.3d at 788. The exemption can only apply to persons "plainly and unmistakably within [its] terms and spirit." *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392 (1960); *Klem v. Cnty. of Santa Clara*, 208 F.3d 1085, 1089 (9th Cir. 2000). Because exemptions are "narrowly construed" against the employer, to meet its burden, an employer must establish that the employee satisfies *each* of the criteria set forth in the Secretary of Labor's regulations. *See Bratt*, 912 F.2d at 1069; *see also Wang v. Chinese Daily News, Inc.*, 623 F.3d 743, 751 (9th Cir. 2010). Reviewing a FLSA exemption is well understood to be "a fact-intensive" inquiry. *Vinole*, 571 F.3d at 945 (citation omitted).

II. Whether Deference to the Secretary's Position is Appropriate

[3] The Secretary's appearance as *amicus* supporting Plaintiffs requires us to determine what, if any, deference we must accord to her view that PSRs do not meet the primary duties test for the outside sales exemption. The Secretary also advocated this construction of the regulations before the Second Circuit in *Novartis*. 611 F.3d at 149. Although the *Novartis* court held that Secretary's interpretation was owed *Auer* deference, 611 F.3d at 153, our review of the relevant authorities leads us to a different conclusion. We conclude that we owe no deference to the Secretary's current interpretation of the regulations, and, in any event, we respectfully disagree with that interpretation.

*2348 A. Administrative Deference in the FLSA

When a question arises as to the meaning of the FLSA or the Secretary's regulations, we apply

traditional rules of construction and, where required, administrative deference. *See, e.g., Webster v. Pub. Sch. Emp. of Wash., Inc.*, 247 F.3d 910, 915 (9th Cir. 2001) (citing *Auer*, 519 U.S. at 457). Thus, if the language of a statute or regulation is unambiguous, we apply the terms as written. *See Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000) ("[D]eference is warranted only when the language of the regulation is ambiguous."); *Chevron,* 467 U.S. at 842-43 ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). By contrast, when Congress has *not* "directly spoken to the precise question at issue," *Auer*, 519 U.S. at 457, we will defer to the Secretary's regulation "so long as it is 'based on a permissible construction of the statute.' " *Id.* (citing *Chevron*, 467 U.S. at 842-43). If the Secretary's regulations are themselves ambiguous, and the Secretary uses her rulemaking authority to provide clarity, we give controlling deference to the Secretary's view unless it is "plainly erroneous or inconsistent with the regulation." *Auer*, 519 U.S. at 461 (citation and internal quotation mark omitted); *see also Christensen*, 529 U.S. at 586-87, 588 ("*Auer* deference is warranted only when the language of the regulation is ambiguous."); *cf. In re Farmers Ins. Exch., Claims Representatives' Overtime Pay Litig.*, 481 F.3d 1119, 1129 (9th Cir. 2007) ("We must give deference to the DOL's interpretation of its own regulations through, for example, Opinion Letters."). Lastly, if the Secretary interprets an *unambiguous* statute by way of an opinion letter, enforcement guidelines, or the like, her opinion is merely "entitled to respect" to the extent the interpretation has the

"power to persuade" the court. *See Christensen*, 529 U.S. at 587 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

2349 B. *In re Novartis Wage & Hour Litigation

In *Novartis*, the Second Circuit held that PSRs did not meet the requirements of the outside sales exemption. As it has done here, the DOL took the position that "when an employee promotes to a physician a pharmaceutical that may thereafter be purchased by a patient from a pharmacy . . . the employee does not in any sense make the sale." *Novartis*, 611 F.3d at 153. In reviewing the Secretary's position, the Second Circuit laid out the relevant statutory and regulatory history and focused its attention on the Secretary's regulations, and, in particular, the Preamble in the 2004 Rule which "emphasized that no one could be considered a salesman within these regulations unless he in some sense made a sale." *Id.* at 152. The *Novartis* court highlighted a series of comment letters sent to the DOL by manufacturers' associations and industry trade groups that had requested "the Department [ ] eliminate the emphasis upon an employee's 'own' sales . . . because of team selling, customer control of order processing, and increasing computerization of sales and purchasing activities. . . ." 69 Fed. Reg. at 22,162. The United States Chamber of Commerce emphasized that "promotional activities, even when they do not culminate in an individual sale, are nonetheless an integral part of the sales process." *Id.* Based on these concerns, the DOL made a "minor change" to "address commenter concerns that technological changes in how orders are taken and processed should not preclude the exemption for

employees whose primary duty is making sales." *Id.* The 2004 Rule continues: "[T]he Department does not intend to change any of the essential elements required for the outside sales exemption, including the requirement that the outside sales employee's primary duty must be to make sales or to obtain orders or contracts for services. An employer cannot meet this requirement unless it demonstrates objectively that the employee, in some sense, has made sales." *Id.*

The *Novartis* court also quoted the Preamble's elaboration of the primary-duty standard: "*Employees have a primary* ****2350*** *duty of making sales if they 'obtain a commitment to buy' from the customer* and are credited with the sale.' " 611 F.3d at 152 (quoting 69 Fed. Reg. at 22,162) (emphasis in original). The Secretary's interpretation is based on a 1949 DOL interpretation, which provided: "In borderline cases the test is whether the person is actually engaged in activities directed toward the consummation of his own sales, at least to the extent of obtaining a commitment to buy from the person to whom he is selling. If his efforts are directed toward stimulating the sales of his company generally rather than the consummation of his own specific sales his activities are not exempt." 69 Fed. Reg. at 22,162-63 (citation omitted).

The Second Circuit determined that the Secretary's regulations "do far more than merely parrot the language of the FLSA." *Novartis*, 611 F.3d at 153. For that reason, "the Secretary's interpretations of her regulations are [ ] entitled to 'controlling' deference unless those interpretations are 'plainly erroneous or inconsistent with the

regulation.' " *Id.* (quoting *Auer*, 519 U.S. at 461 (internal quotation omitted)). The *Novartis* court could find no inconsistencies or errors in the Secretary's *amicus* position. *Id.* The court stated it did not believe the distribution practices of the drug company constituted an "other disposition," as that term is used in the FLSA. Rather, the court said that because "other disposition" followed a line of words which, apparently, emphasized "a sale" being consummated, "other disposition" was not intended as a "catch-all" category. *Id.* Ultimately, the *Novartis* court summarized its reasoning:

> [W]here the employee promotes a pharmaceutical product to a physician but can transfer to the physician nothing more than free samples and cannot lawfully transfer ownership of any quantity of the drug in exchange for anything of value, cannot lawfully take an order for its purchase, and cannot lawfully even obtain from the physician a binding commitment to prescribe it, we conclude that it is not plainly ***2351** erroneous to conclude that the employee has not in any sense, within the meaning of the statute or the regulations, made a sale.

Id. at 154.

C. Deference Owed in this Case

[4] Our view of the level of deference we owe to the Secretary in this matter is best captured by the Supreme Court's instruction in *Gonzales v. Oregon*: "An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a

regulation, it has elected merely to paraphrase the statutory language." 546 U.S. 243, 257 (2006); *see also Chase Bank USA, N.A. v. McCoy*, 562 U.S. ___, (slip op. at 15) (Jan. 24, 2011) ("Accordingly, no deference was warranted to an agency interpretation of what were, in fact, Congress' words."); *N. Cal. River Watch v. Wilcox*, 620 F.3d 1075, 1088 (9th Cir. 2010) ("Here, the three rules cited by the United States essentially parrot the statutory language."). The "parroting" with which the *Gonzales* Court took issue is present in the Secretary's interpretation of Section 3(k).

According to the Secretary's regulations, a salesman is someone who either "mak[es] sales within the meaning of section 3(k) of the Act" or someone who "obtain[s] orders or contracts." 29 C.F.R. 541.500(a)(1). Since there is no dispute that PSRs do not obtain orders for anything, only the "sales" element is relevant here. To define "sales within the meaning of section 3(k)," we look to 29 C.F.R. § 541.501(b), which provides that "[s]ales within the meaning of section 3(k) of the Act include the transfer of title to tangible property, and in certain cases, of tangible and valuable evidences of intangible property." Section 3(k) of the Act states that " '[s]ale'" or 'sell' includes any sale, exchange, contract to sell, consignment for sale, shipment for sale, or other disposition." 29 U.S.C. § 203(k). Thus, the Secretary has given us two mean-*2352ings with which to set the boundaries of the sales exemption. First, in 29 C.F.R. § 541.501(b), the Secretary provides an open-ended definition that sales, unsurprisingly, "include the transfer of title to tangible property." In the next sentence, the Secretary cross-references back to the language of

Section 3(k) of the Act—the very language purportedly being defined. Accordingly, the Secretary's regulations define "sale" or "sell" by statutory renvoi—that is, a "sale" means a "sale." This clarifies nothing about the meaning of Section 3(k); it merely incorporates the very undefined, very un-delimited term the Secretary seeks to clarify. A definition dependent almost entirely on Congress's seventy-two-year old statutory language is not an example of the DOL employing its "expertise" to elucidate meaning to which we owe *Auer* deference. *See N. Cal. River Watch*, 620 F.3d at 1085-87.

In *Gonzales v. Oregon*, the Supreme Court confronted an analogous situation when it rejected the Attorney General's regulatory attempt to frustrate the implementation of Oregon's Death with Dignity Act. In that case, Oregon statutory law exempted licensed physicians from liability when they prescribed medication to hasten death for terminally ill individuals. 546 U.S. at 249-54. In 2001, shortly after a change of presidential administration, the Attorney General promulgated a new interpretive rule that restricted the use of controlled substances in physician-assisted suicides. *Id.* at 254. In defending that rule, the government contended in its appeal that the judiciary was required to give "considerable deference" to the Attorney General's interpretive rule as it was "an elaboration of one of [his] own regulations." *Id.* at 256. In rejecting that contention, the Supreme Court drew meaningful distinctions with its decision in *Auer*:

> In *Auer*, the underlying regulations gave specificity to a statutory scheme the

> Secretary was charged with enforcing and reflected the considerable experience and expertise the [DOL] had acquired over time. . . .***2353** *Here, on the other hand, the underlying regulation does little more than restate the terms of the statute itself.* The language the Interpretive Rule addresses comes from Congress, not the Attorney General, and the near equivalence of the statute and regulation belies the Government's argument for *Auer* deference.

Id. at 256-57 (emphasis added).

[5] The failure to add specificity to the statutory scheme that troubled the *Gonzales* Court, indeed the "parroting" of statutory language, is present in the Secretary's outside sales regulations. Rather than setting forth a particular test for "sale" or instructing employers to look for indicia of sales, the Secretary's regulations direct employers, employees, and this court back to the language of the FLSA. Given the admonition in *Gonzales*, we are unable to accord *Auer* deference to a regulation written in this manner.

[6] Thus, when we look to the Secretary's brief for her application of the regulations, we see only a *reinterpretation* of Section 3(k). Rather than applying the regulation to the facts presented, the Secretary has used her appearance as *amicus* to draft a new interpretation of the FLSA's language. Were we to accept the Secretary's offer, and give controlling deference even where there exists no meaningful regulatory language to interpret, we would unduly expand *Auer*'s applicability to interpretations of statutes expressed for the first time in case-by-case

amicus filings. *See N. Cal. River Watch*, 620 F.3d at 1088 ("In this case, the *amicus* brief purports to interpret statutory, not regulatory, language."). In essence, we would sanction bypassing of the Administrative Procedures Act and notice-and-comment rulemaking. *C.f. Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) ("Here, however, we confront an interpretation contained in an opinion letter, not one arrived at after, for example, a formal adjudication or notice-and-comment rulemaking."). Accordingly, we hold ***2354** that we need not give "controlling" deference to the Secretary's interpretations in this matter.[7] Furthermore, even if *Auer* applied, deference is not warranted because the Secretary's position is both plainly erroneous and inconsistent with her own regulations and practices, as demonstrated in the analysis that follows.

III. "Sales" and "Selling" in the Pharmaceutical Industry

Absent an agency-determined result, it is the province of the court to construe the relevant statutes and regulations. *N. Cal. River Watch*, 620 F.3d at 1088-89. As noted *supra*, Plaintiffs argue that by not transferring any product to physicians, they are not selling pharmaceuticals, but only "promoting" them. Plaintiffs say this distinction is warranted in light of the rule that the FLSA be "narrowly construed against . . . employers." *Webster*, 247 F.3d at 914. For its part, Glaxo urges us to view "sale" in Section 3(k) in a commonsensical fashion,

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[7] As explained *infra*, we likewise find unpersuasive the Secretary's interpretation of the FLSA provisions, thus vitiating any *Skidmore* deference. *See* Section III.

while contending that the meaning of "sale" is permissive. Glaxo urges us to adopt the rationale that the phrase "other disposition" in Section 3(k)'s definition of "sale" is a broad catch-all category.[8] This view was cited with approval by the district court here, and is supported by the Secretary's usage, dating back to 1940, of the language that an employee must "*in some sense* make a sale." 69 Fed. Reg. at 22,162 (quoting "Executive, Administrative, Professional Outside Salesman" Redefined, Wage and Hour Division, U.S. Dept. of Labor, Report & Recommendations of the Presiding Officer ***2355** (Harold Stein) at Hearings Preliminary to Redefinition, at 46 (Oct. 10, 1940)) (emphasis added).

[7] Plaintiffs' contention that they do not "sell" to doctors ignores the structure and realities of the heavily regulated pharmaceutical industry. It is undisputed that federal law prohibits pharmaceutical manufacturers from directly selling prescription medications to patients. Plaintiffs suggest that despite being hired for their sales experience, being trained in sales methods, encouraging physicians to prescribe their products, and receiving commission-based compensation tied to sales, their job cannot "in some sense" be called selling. This view ignores the reality of the nature of

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[8] *See* Steven I. Locke, *The Fair Labor Standards Acts Exemptions and the Pharmaceuticals Industry: Are Sales Representatives Entitled to Overtime?*, 13 Barry L. Rev. 1, 25 (2009) ("Applying these [common-usage] definitions, it is logical to conclude that the term 'other disposition,' as it is used to define a 'sale' under the Act, includes a physician's decision to write a prescription for a particular medication.").

the work of detailers, as it has been carried out for decades. Plaintiffs' argument also fails to account for the fact that the relevant "purchasers" in the pharmaceutical industry, and the appropriate foci of our inquiry, are not the end-users of the drug but, rather, the prescribing physicians whom they importune frequently. *See, e.g.*, *Baum v. AstraZeneca LP*, 605 F. Supp. 2d 669, 678-79 (W.D. Pa. 2009) (discussing why the "professional paradigm" places the physician as the relevant decision maker in the health services industry), *aff'd on other grounds*, 372 Fed. App'x 246 (3d Cir. 2010). Unlike conventional retail sales, the patient is not at liberty to choose personally which prescription pharmaceutical he desires. As such, he cannot be fairly characterized as the "buyer." Instead, it is patient's physician, who is vested with both a moral and legal duty to prescribe medication appropriately, who selects the medication and is the appropriate focus of our "sell/buy" inquiry. In this industry, the "sale" is the exchange of non-binding commitments between the PSR and physician at the end of a successful call. Through such commitments, the manufacturer will provide an effective product and the doctor will appropriately prescribe; for all practical purposes, this is a sale. Because pharmaceutical manufacturers appreciate who the "real" buyer is, they have structured their 90,000-person sales force and their marketing tactics to accommodate this unique environment.

***2356 [8]** When a PSR visits a doctor, he or she attempts to obtain the absolute maximum commitment from his or her "buyer"—a non-binding commitment from the physician to prescribe the PSR's assigned product when medically appropriate.

In most industries, there are no firm legal barriers that prohibit the *actual physical* exchange of the goods offered for sale. Because such barriers do exist in this industry, the fact that commitments are non-binding is irrelevant; the record reveals that binding or non-binding, a physician's commitment to a PSR is nevertheless a meaningful exchange because pharmaceutical manufacturers value these commitments enough to reward a PSR with increased commissions when a physician increases his or her use of a drug in the PSR's bag. *See, e.g.*, *Baum*, 605 F. Supp. 2d at 681 ("This Court believes that other courts, and perhaps regulatory agencies, underestimate the significance of this oral commitment from physicians. In part, this error emerges from a misunderstanding of the ways in which human beings are socially and informally motivated. Sometimes lawyers and judges forget that a person's word means something; remarkably, many people do not actually need a 400-page contract to bind themselves to their word.").

Moreover, the industry has agreed upon and abides by the PhRMA Code to regulate the marketing of medicine to healthcare professionals—just as any consumer-products maker might develop rules to limit the express warranties its sales force might offer to a customer. Such industry practice and prevailing customs should inform our disposition. *Cf. Reiseck v. Universal Commc'ns of Miami, Inc.*, 591 F.3d 101, 106 (2d Cir. 2010) (in resolving whether advertising sales director was an administrative or sales worker in the publishing industry "a careful consideration of [employer's] business model provides some clarity").

Under Plaintiffs' view, PSRs are not salespeople, despite the fact that more than 90,000 pharmaceutical representatives make daily calls on physicians for the purpose of driving ***2357** greater sales. *See IMS Health*, 616 F.3d at 14. We cannot square this view with Section 3(k)'s open-ended use of the word "sale," which *includes* "other disposition[s]." While we recognize that the FLSA is to be narrowly construed in light of its remedial nature, that general principle does not mean that every word must be given a rigid, formalistic interpretation. For example, for over seventy years, the Secretary has emphasized a sensible application of the exemptions; in the Preamble to the 2004 Rule, the Secretary employs the open-ended concept that a salesman is someone who "in some sense" sells. 69 Fed. Reg. at 22,162-63 (emphasis added). In other words, while the Secretary asks us to narrowly interpret this exemption, she herself acknowledges that technical considerations alone and changes in the way sales are made should not be grounds for denying the exemption. *See* 69 Fed. Reg. at 22,162.

To further explain our common sense understanding of why PSRs make sales, we find the paradigm "outside salesman" case *Jewel Tea Co. v. Williams*—instructive. 118 F.2d 202 (10th Cir. 1941). The importance of *Jewel Tea* is illustrated by the fact that both parties and the *amicus* offer it as favorable precedent for their conflicting positions.

Jewel Tea involved a FLSA overtime-wage suit brought by three employees of a tea, coffee, and sundry goods manufacturer and distributor. 118 F.2d at 203. The plaintiffs held the position of "route salesmen" to "sell and distribute" products to

customers in their homes. *Id.* The area in which the company sold its goods was divided and "[e]ach salesman [was] assigned an exclusive territory which he cover[ed]." *Id.* The employees made no immediate deliveries but instead took orders for future delivery, although they might advance an item to a customer. *Id.* The company provided sales training and sent a supervisor with a new hire on early sales calls before permitting the employee to "go out on a route by himself." *Id.* at 204. Further, employees were taught a "five-point sale" method to employ when speaking with customers. *Id.* A ***2358** certain degree of knowledge about the products and potential customers was also required—"[t]he salesman must know recipes for the preparation of the Company's products . . . [and] must learn the general requirements of each family, in order to avoid over-stocking his customer and in order to anticipate the family's needs." *Id.* After working in the field during the day, employees completed some clerical tasks at night. *Id.* at 205. Finally, employees were paid a base salary plus a commission if their collections were in excess of a sum certain. *Id.*

The *Jewel Tea* plaintiffs brought suit to collect unpaid overtime, asserting they did not fall within the "outside sales" exemption, primarily employing the argument that they were "delivery men." *Id.* at 208. In its decision denying plaintiffs overtime pay, the Tenth Circuit penned the oft-quoted justification for the outside sales exemption:

> The reasons for excluding an outside salesman are fairly apparent. Such salesman, to a great extent, works individually. There are no restrictions

> respecting the time he shall work and he can earn as much or as little, within the range of his ability, as his ambition dictates. In lieu of overtime, he ordinarily receives commissions as extra compensation. He works away from his employer's place of business, is not subject to the personal supervision of his employer, and his employer has no way of knowing the number of hours he works per day. To apply hourly standards primarily devised for an employee on a fixed hourly wage is incompatible with the individual character of the work of an outside salesman.

Id. at 207-08.

[9] Reviewing the undisputed facts here, we consider the rationale for applying the outside sales exemption to PSRs to be as "apparent" as it was in *Jewel Tea*. Of course, this case ***2359** does not involve door-to-door consumer-product sales. But, the FLSA is not an industry-specific statute. As the Second Circuit recognized in *Reiseck*, not all FLSA claims will involve the "archetypal businesses envisaged by the FLSA," 591 F.3d at 106. Even though there are differences, it is notable that the salesmen in *Jewel Tea* and Plaintiffs here each (1) worked in assigned territories, (2) did not make immediate deliveries, (3) were required to analyze client backgrounds, (4) received product training, (5) employed a pre-planned routine for client interaction, (6) were accompanied by supervisors for training, (7) were later subject to minimal supervisor oversight, (8) completed clerical activities at the end of the day, and (9) had a dual salary and commission-

based compensation plan tied to their performance. Even though PSRs lack some hallmarks of the classic salesman, the great bulk of their activities are the same, as is the overarching purpose of obtaining a commitment to purchase (prescribe) something.

[10] The primary duty of a PSR is not promoting Glaxo's products in general or schooling physicians in drug development. These are but preliminary steps toward the end goal of causing a particular doctor to commit to prescribing *more* of the particular drugs in the PSR's drug bag. Without this commitment and the concomitant increase in prescriptions, or drug volume, or market share—i.e. without more *sales*—the PSR would not receive his or her commission salary and could soon find himself or herself unemployed. While not all steps in the PSR's daily activities constitute "selling," that fact does not render the totality of those activities non-exempt promotion; "work performed incidental to and in conjunction with the employee's own outside sales or solicitations . . . shall be regarded as exempt outside sales work . . . [and] . . . other work that furthers the employee's sales efforts also shall be regarded as exempt work." 29 C.F.R. § 541.500(b).

The Secretary's distinction between selling and promoting is only meaningful if the employee does not engage in *any* activities that constitute "selling" under the Act. This much is ***2360** seen from the plain language of the regulations, which gives the example of promotional work as "a company representative who visits chain stores, arranges the merchandise on shelves, replenishes stock by replacing old with new merchandise, sets up displays and consults with the store manager when

inventory runs low, but *does not obtain a commitment for additional purchases.*" 29 C.F.R. § 541.503(c) (emphasis added). PSRs do far more than collect general data or provide consultations; indeed they ask for, and sometimes obtain, a commitment by the doctor to prescribe Glaxo drugs, and whether the doctor keeps that commitment is verified and traced using aggregated pharmacy data Glaxo collects. *See IMS Health*, 550 F.3d at 44-47 ("A valuable tool in this endeavor, available through the omnipresence of computerized technology, is knowledge of each individual physician's prescribing history.").

In *Reisick*, the Second Circuit highlighted an important distinction between selling and promoting, noting that the latter is directed to the public at large, as opposed to a particular client:

> Consider a clothing store. The individual who assists customers in finding their size of clothing or who completes the transaction at the cash register is a salesperson under the FLSA, while the individual who designs advertisements for the store or decides when to reduce prices to attract customers is an administrative employee for the purposes of the FLSA.

Reiseck, 591 F.3d at 107. At Glaxo, Plaintiffs had no interest in "generally" promoting sales by the company or improving sales across the board. Rather, Plaintiffs directed their sales efforts only towards certain products, only to a discrete group of physicians, and only within a defined geographic area. Targeting physicians is not based on mass appeals or general advertisements, but is the result

of a personalized review of *2361 each physician's prescribing habits and history. The process, like any sales process, is *tailored* to the customer's preferences.

[11] We also find that the Secretary's acquiescence in the sales practices of the drug industry for over seventy years further buttresses our decision. The outside sales exemption has existed since 1938. Detail men have practiced their craft over that same period. Generally, they have been considered salespeople.[9] Until the Secretary's

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[9] *See N. Cal. Pharm.*, 306 F.2d at 386 (9th Cir. 1962) (" 'Detail men,' or local sales representatives. . ."); *see also IMS Health*, 550 F.3d at 54 ("In the service of *maximizing drug sales*, detailers use prescribing histories as a means of targeting potential customers more precisely and as a tool for tipping the balance of bargaining power in their favor. As such, detailing affects physician behavior and increases the likelihood that physicians will prescribe the detailers' (more expensive) drugs." (emphasis added)); *Williams v. Bristol-Myers Squibb,* Co., 85 F.3d 270, 273 (7th Cir. 1996) ("Federal law requires a maker of prescription drugs to have a samples control program designed to prevent its salesmen, who frequently give free samples to the physicians they call on, from distributing prescription drugs outside authorized channels."); *Sun Ray Drug*, 320 F.2d at 74 ("efforts on the part of its detail men (who are salesmen)"); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1377 (S.D. Fla. 2007) ("In each of these cases, the courts found that the drugs were overpromoted by salesmen known as 'detail men,' who visited physicians' offices and encouraged physicians to prescribe the drug."); *Skill v. Martinez*, 91 F.R.D. 498, 508 (D.N.J. 1981) ("comments by drug "'detail men' (drug salesmen who visit physicians)"); *Smith, Kline & French Lab. v. State Tax Comm'n*, 403 P.2d 375, 378 (Or. 1965) ("By soliciting the

appearance in *Novartis*, the DOL did not challenge the conventional wisdom that detailing is the functional equivalent of selling pharmaceutical products. Indeed, the DOL has recognized as much in its Dictionary of Occupation Titles, which provides the following definition for pharmaceutical detailers:

> ***2362** Promotes use of and *sells* ethical drugs and other pharmaceutical products to physicians, [dentists], hospitals, and retail and wholesale drug establishments, utilizing knowledge of medical practices, drugs, and medicines: Calls on customers, informs customer of new drugs, and explains characteristics and clinical studies conducted with drug. Discusses dosage, use, and effect of new drugs and medicinal preparations. Gives samples of new drugs to customer. Promotes and *sells* other drugs and medicines manufactured by company. May sell and take orders for pharmaceutical supply items from persons contacted.

D.O.L. Dictionary of Occupational Titles § 262.157-010 (4th ed. 1991) (emphases added). Likewise, although it emerged in a different context, we find Judge Posner's observation in *Yi v. Sterling Collison Centers, Inc.*, 480 F.3d 505, 510-11 (7th Cir. 2007), informative—while it is "possible for an entire industry to be in violation of the [FSLA] for a long

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stocking of plaintiff's products by druggists and the prescription of those drugs by physicians, plaintiff 's detail men perform the same sales function in plaintiff's field that salesmen soliciting actual orders from the ultimate user perform in other businesses.").

time without the Labor Department noticing[, the] more plausible hypothesis is that the . . . industry has been left alone" because DOL believed its practices were lawful.

[12] In view of many similarities between PSRs and salespeople in other fields, pharmaceutical industry norms, and the acquiescence of the Secretary over the last seventy-plus years, we cannot accord even minimal *Skidmore* deference to the position expressed in the *amicus* brief. Under *Skidmore*, "[t]he fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position." *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (internal citations omitted); *see also League of Wilderness Defenders v. Forsgren*, 309 F.3d 1181, 1189 (9th Cir. 2002) (quoting *Skidmore*, 323 U.S. at 140) (internal quotation marks omitted). Many, if not all, ***2363** of these hallmarks of "respectful" deference are absent here. The about-face regulation, expressed only in ad hoc *amicus* filings, is not enough to overcome decades of DOL nonfeasance and the consistent message to employers that a salesman is someone who "in some sense" sells. Moreover, we are unable to accept an argument that fails to account for industry customs and emphasizes formalism over practicality, in particular the argument that "obtaining a commitment to buy" is the *sine qua non* of the exemption. Under the Secretary's view, "sale" means unequivocally the final execution of a legally binding contract for the exchange of a discrete good. In addition to the point

that such stringent wording is not found in Section 3(k), or plausibly implied from phrases like "other disposition," the Secretary's approach transforms what since the time of *Jewel Tea* has been recognized as a multifactor review of an employee's functions into a single, stagnant inquiry.

Telephones, television, shopping malls, the Internet and general societal progress have largely relegated the professional pitchman embodied in *Jewel Tea* to the history books. But selling continues, and, as in prior eras, a salesperson learns the nuances of a product and those of his or her potential clientele, tailors a scripted message based on intuition about the customer, asks for the customer to consider her need for the product, and then receives a commission when the customer's positive impression ultimately results in a purchase.

[13] For the past seventy-plus years, selling in the pharmaceutical industry has followed this process. PSRs are driven by their own ambition and rewarded with commissions when their efforts generate new sales. They receive their commissions in lieu of overtime and enjoy a largely autonomous work-life outside of an office. The pharmaceutical industry's representatives—detail men and women—share many more similarities than differences with their colleagues in other sales fields, and we hold that they are exempt from the FLSA overtime-pay requirement.

*2364 CONCLUSION

For the foregoing reasons, we AFFIRM the district court's summary judgment for Defendant-Appellee SmithKline Beecham Corporation.

AFFIRMED.

Supreme Court, U.S.
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No. 10-459

IN THE

Supreme Court of the United States

SCHERING CORPORATION,

Petitioner,

v.

EUGENE KUZINSKI, MARC CAMPANO, JERRY HARRIS, AND SHAWN JONES, ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Schering Corporation ("Schering") has petitioned the Court to review the ruling by the Second Circuit that pharmaceutical sales representatives are not exempt outside salespersons under the Fair Labor Standards Act. An important question of federal law is raised by the ruling—namely, whether *Auer* deference should be extended to an agency's interpretation of statutory language stated for the first time in an unsolicited *amicus* brief when that interpretation causes unfair surprise and imposes substantial liability on not only the pharmaceutical industry, but also any industry that employs outside sales representatives.[1] As shown below, Respondents' attempts to challenge the bases for certiorari fall short and the Court's review is warranted.

A. This Case Involves An Important Question of Federal Law.

The Second Circuit's decision has far-reaching consequences for the pharmaceutical industry, including the potential for enormous retroactive

[1] Schering's appeal was heard in tandem with *In re Novartis Wage & Hour Litigation*, 611 F.3d 141 (2d Cir. 2010) (App. C at 45a) ("*Novartis*"). The Department of Labor ("DOL") appeared *sua sponte* in *Novartis* on behalf of the plaintiffs. (App. M at 110a) In an opinion that dictated the result in Schering's appeal, the Second Circuit in *Novartis* deferred to DOL's interpretation of the outside sales and administrative exemptions and ruled that the plaintiffs were not exempt employees. Novartis filed its petition for writ of certiorari on October 4, 2010. (No. 10-460).

liability for back overtime pay and the upheaval associated with a major restructuring of the sales forces of all pharmaceutical companies — all because of an abrupt and unexpected change in DOL's interpretation of its regulations announced for the first time in an *amicus* brief. Brief of Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amicus Curiae* in Support of Petitioner at 23-25, *Novartis Pharms. Corp. v. Lopes*, No. 10-460 ("PhRMA Brief"); *see also* Pet. 2, 14-19. Nor will the impact be limited to the pharmaceutical industry. The Second Circuit's decision upsets decades of settled law on the meaning of the word "sale," creating uncertainty for employers in nearly every sector of the American economy." Brief of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioner at 22, *Novartis Pharms. Corp. v. Lopes*, No. 10-460 ("Chamber Brief"). Respondents do not dispute this far-reaching impact, nor can they.

Instead, Respondents argue the interpretation of the outside sales exemption "urged" by Schering will "swallow the rule." Opp. 15. Schering, however, does not advocate an interpretation which would "include all employees engaged in activities designed to increase demand for their employer's goods or services" as Respondents suggest, nor one which would cover employees "wearing sandwich boards on the sidewalk." *Id.* Such suggestions, as well as Respondents' comparison of pharmaceutical sales representatives (who play an integral role in the provision of healthcare to patients) with a cereal company's popular mascot, are merely meant to distract the Court from the widespread and deleterious consequences of the Second Circuit's ruling, affecting

substantially more employees and industries than Respondents admit. Pet. 2, 14-19; PhRMA Brief, at 23-25; Chamber Brief, at 22.

B. The Court's Guidance Is Needed To Clarify *Auer* Deference.

Respondents argue that the scope of deference to be afforded an agency's interpretation of its own regulations is "plain and unambiguous" under *Auer v. Robbins*, 519 U.S. 452 (1997), and that the Court's guidance is not needed to clarify *Auer*'s limits in the circumstances present here. Opp. 21-22. Respondents' conclusory arguments aside, application of *Auer* deference in this case is far from "plain and unambiguous."

As a threshold matter, *Auer* requires that the regulation at issue be ambiguous. 519 U.S. at 463. Neither DOL nor the Second Circuit identified an ambiguity in the regulations, and the court made no reference to that requirement in its ruling. The failure to address this threshold issue only serves to underscore the need for clarification of when *Auer* deference should apply.

Nor is it clear that the court's analysis is consistent with the limits on *Auer* deference established under *Gonzales v. Oregon*, 546 U.S. 243 (2006). The question of whether any of the millions of sales representatives employed in the United States are properly classified as exempt outside salespersons turns on the meaning of "sale." Rather than delegating the matter to DOL, Congress itself defined the word "sale" in expansive terms, 29 U.S.C. § 203, and DOL expressly adopted that definition in its implementing regulations, 29 C.F.R. § 541.500. Under *Gonzales*, courts should not defer to an agency's

interpretation of language that merely paraphrases the statute. 546 U.S. at 257. On its face, therefore, deference to DOL's interpretation of "sale" appears unwarranted, and the court's conclusion to the contrary by relying on non-definitional regulations separate from the definition of "sale" creates uncertainty as to the interplay between *Gonzales* and *Auer*. Pet. at 20-21.

Most importantly, this case presents the unsettled issue of *Auer*'s role where an agency's informal interpretation, here in an unsolicited *amicus* brief, creates unfair surprise and the potential for massive and unanticipated liability. Pet. 15-19. *Long Island Care at Home, Ltd. v. Coke* suggests that courts should not accord "controlling" deference to an agency's interpretation in such circumstances. 551 U.S. 159, 171 (2007). *Coke,* however, had no cause to elaborate on this dictum because DOL's change in interpretation there came about after only notice-and-comment rulemaking. *Id.* The Second Circuit's failure to address the unfair surprise and unanticipated liability arising from DOL's interpretation in *Novartis* underscores the uncertainty that remains after *Auer* and the need for the Court's guidance.

C. DOL's New Interpretation Creates Unfair Surprise.

In their effort to show that there was no unfair surprise here, Respondents contend that "no one" could have read the agency's regulations and concluded that pharmaceutical sales representatives are exempt outside salespersons. Opp. 20. They reach that conclusion despite the expansive definition of the word "sale" and DOL's consistent instruction for 70 years that a sales employee only

had to make sales "in some sense" to be exempt. The notion that the industry should have known better is belied by numerous lower court rulings that applied DOL's pre-*Novartis* guidance and found that pharmaceutical sales representatives make sales under both the FLSA and state laws that look to the FLSA for guidance, the existence of which caused the trial court to certify interlocutory appeal in this matter. Pet. 18, n.2.

DOL has long acknowledged that an employee engages in "sales" as defined by § 203(k) of the FLSA whenever the employer can demonstrate "that the employee, in some sense, has made sales." 69 Fed. Reg. 22122, 22162 (Apr. 23, 2004) (citing 1940 Stein Report at 46) (App. L at 104a-105a)). Before the filing of DOL's *amicus* brief in *Novartis*, there was no requirement that the employee engage with the customer in a direct exchange of goods for consideration, as long as the employee "in some sense" made sales. With its *amicus* brief, however, DOL abandoned the flexible understanding of the meaning of a "sale" and imposed a new requirement that a direct exchange of a good for consideration occur between the employee and customer. Because of the regulatory constraints that prohibit a direct exchange of pharmaceutical drugs to be made between a pharmaceutical sales representative and a physician's patients, that interpretation makes it impossible for pharmaceutical companies to classify *any* employees as outside salespersons, even when those employees perform every other traditional function of the job. It no longer is enough that those employees make sales in the only sense in which sales can be made in the pharmaceutical industry.

Despite this shift, Respondents assert that "[t]here has been no change" from DOL's past position, and thus no unfair surprise, as to what constitutes a "sale" for the purposes of the outside sales exemption. Opp. 16-20. To support this proposition, Respondents cite to inapplicable precedent and selectively cite (and in some instances, misquote) regulatory language.

1. Respondents' authority fails to rebut the unfair surprise caused by DOL's new interpretation.

Respondents continue to ignore the nature of the pharmaceutical industry, including the reality of what a "sale" is in that context. Their authority misses the mark because pharmaceutical sales representatives do not merely pave the way for others to complete the transaction and do not sell a theoretical concept.

Two cases relied upon by Respondents were cited in *Novartis* and were already distinguished in Schering's Petition. Pet. 28, n.5. These cases both involved employees who paved the way for "sales" to be "closed" by other employees, a business model which differs materially from that of the pharmaceutical industry. *See Clements v. Serco, Inc.*, 530 F.3d 1224 (10th Cir. 2008) (civilian recruiters were not exempt where they "merely cultivated 'a list of persons who seem[ed] receptive to the idea' of joining the Army" and others evaluated and enlisted the accepted candidates); *Wirtz v. Keystone Readers Serv., Inc.*, 418 F.2d 249 (5th Cir. 1969) ("student salesmen" who were employed to make the first contact with potential customers were not exempt;

they were engaged in activities incidental to sales made by managers).[2]

Respondents' reliance on certain DOL Opinion Letters is similarly misplaced. Pharmaceutical sales representatives are not like college enrollment advisors who only meet with prospective students "selling them on attendance at school." WH Opinion Letter FLSA, 1998 DOLWH LEXIS 17 (Feb. 19, 1998) (Opp. 5, n.3). Nor are they remotely comparable to solicitors of charitable donations or liaisons between organ donors and non-profit foundations. Those employees' duties are akin to those of outside buyers, the opposite of outside salespersons. *See* WH Opinion Letter FLSA 2006-16, 2006 DOLWH LEXIS 65 (May 22, 2006) (selling the concept of donating to a charity did not qualify as sales); WH Opinion Letter FLSA, 1994 DOLWH LEXIS 65 (Aug. 19, 1994) (selling the concept of tissue donation did not qualify for the outside sales exemption). Schering's pharmaceutical sales representatives do not sell a theoretical concept. Rather, they work to secure a physician's commitment to prescribe a specific product for appropriate patients, and the physician

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[2] The comparison of pharmaceutical sales representatives to the manufacturer's representative who does preliminary work, such as encouraging a retailer to buy the manufacturer's products, likewise fails. In the case of the manufacturer's representative, a distributor's salesperson actually follows the representative to the retailer and takes the retailer's order. Opp. 18-19. There is no one like the distributor's salesperson in the sale of prescription drugs; no one from a pharmaceutical wholesaler follows a pharmaceutical sales representative into a doctor's office to "take the order" from the physician.

places the order for the product by writing the prescription.[3]

2. To create the false impression that DOL's new interpretation does not represent a change in position, Respondents misquote the regulations.

Respondents cite "instructive examples" in the regulations which allegedly support DOL's interpretation of the exemption. Opp. 4-5. Analogizing pharmaceutical sales representatives to a company's representative who visits chain stores to monitor inventory, for example, Respondents state "[b]ecause the employee in this instance does not *consummate the sale* . . . the work is not exempt outside sales work." Opp. 5 (citing 29 C.F.R. § 541.503 (c) (emphasis supplied by Respondents)). The words omitted by the use of ellipses, however, prove the fallacy of the argument. The regulation actually states the following: "Because the employee in this instance does not consummate the sale *nor direct efforts toward the consummation of a sale*, the work is not exempt outside sales work." 29 C.F.R. § 541.503 (c) (emphasis supplied). Even if pharmaceutical sales representatives cannot "consummate" a sale in the technical sense now required by the

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[3] The Opinion Letters do not mandate that the employee consummate a direct sale to be classified as an outside salesperson. The 1994 Opinion Letter analyzing the position of tissue recovery coordinators, for example, explained that exempt work "includes the sale of commodities" but did not require that the sale occur by a direct exchange between the salesperson and customer. 1994 DOLWH LEXIS 65.

Second Circuit and DOL, they unquestionably direct their efforts towards the consummation of a sale.

In further support of their contention that DOL's interpretation is nothing new, Respondents misstate another key regulatory term. Elaborating upon the statutory requirement of a "sale" under Section 3(k) of the FLSA, Respondents allege that the "regulations further specify that sales under the act *involve* the 'transfer of title to tangible property, and in certain cases tangible and valuable evidence of intangible property.'" Opp. 4 (emphasis added). The regulation actually provides that sales within the meaning of the FLSA "*include* the transfer of title to tangible property." 29 C.F.R. § 541.501(b) (emphasis added). Respondents' use of the word "involve" suggests that the following reference to a transfer of title is mandatory. The word "include" shows that the regulation's reference to the transfer of title is not mandated. Respondents' reliance on selective excerpts and misstatement of relevant regulations serve only to confirm that DOL's new interpretation materially changes the outside sales exemption.

CONCLUSION

After *Auer*, *Coke*, and *Gonzales*, questions remain as to the deference afforded to an agency interpretation. *Coke* instructs that there is no unfair surprise when an interpretation is advanced through notice-and-comment rulemaking (which also suggests that the agency has exercised its considered judgment in advancing the interpretation), but that is not the case here. In the Second Circuit, an uninvited brief, which adds a new twist to established regulations and threatens massive and unanticipated liability sufficient to upend an entire

industry, does not establish unfair surprise. The Court's guidance is needed to clarify the standard required to show unfair surprise, the proof a party must muster to show that an interpretation was not the result of the considered judgment of the agency, and the extent to which a court may look beyond the terms being interpreted to determine whether the agency's interpretation warrants deference. For the foregoing reasons and those stated in the Petition, Schering Corporation's Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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